

US3022291 (Prod: Meridian Clinical Research)

Generated By: (b) (6)

Generated On: 26 Nov 2020 08:40:41

All time stamps listed in this document are displayed in GMT

US3022291

Form: Participant Creation

Generated On: 26 Nov 2020 08:40:41

[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 08:40:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

Date of Birth (MMM yyyy)	(b) (6) 1975
Age	45
Age Units	YEARS
Age (Derived)	45
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input checked="" type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

Date of Informed Consent (<i>dd MMM yyyy</i>)	24 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 08:40:41

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 08:40:41

[Were any significant conditions reported?](#)

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:40:41

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

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:40:41

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:40:41

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:40:41

Condition	GASTRIC BYPASS
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:40:41

Condition	STOMACH ULCER SURGERY
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:40:41

Condition	STOMACH ULCER
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:40:41

Condition	OBESITY
Start date (dd MMM yyyy)	(b) (6) 1975
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)	(b) (6) 1975
Start Year (derived)	1975
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	08:09 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 08:09
Height (<i>xxx.x</i>)	171 cm
Weight (<i>xxx.x</i>)	118.2 kg
BMI (<i>xxx.x</i>)	40.42269 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:40:41

Date of assessment (*dd MMM yyyy*) 24 AUG 2020

Is the participant of childbearing potential? Yes ☒ No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	24 AUG 2020
Test performed	Urine <input type="radio"/>
	Serum <input checked="" type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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 08:40:41

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	True
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	LIVES 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 08:40:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:41

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 144809

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 08:40:41

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 08:40:41

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)	24 AUG 2020
Time of assessment (00:00-23:59)	08:09 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 08:09
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 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 08:40:41

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)	24 AUG 2020
Time of assessment (00:00-23:59)	10:50 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 10:50
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (*dd MMM yyyy*) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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)	24 AUG 2020
What was the treatment time? (00:00-23:59)	10:17 (24 HR)
Treatment Date and Time (derived)	24 AUG 2020 10:17
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 08:40:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	24 AUG 2020
Collection time (<i>00:00-23:59</i>)	09:12 (24 HR)
Collection date and time (derived)	24 AUG 2020 09:12

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:40:41

Collection date (<i>dd MMM yyyy</i>)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:50	24 AUG 2020 08:50
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

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 08:40:41

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

24 AUG 2020 10:51

PC Open Date & Time

24 AUG 2020 10:37

PC Close Date & Time

24 AUG 2020 13:07

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 09:22

PC Open Date & Time

24 AUG 2020 14:02

PC Close Date & Time

25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

26 AUG 2020 05:29

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 00:25

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °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

27 AUG 2020 20:04

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

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

97.3 °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

29 AUG 2020 07:55

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 08:26

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

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

94.3 °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

30 AUG 2020 22:22

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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

24 AUG 2020 10:52

PC Open Date & Time

24 AUG 2020 10:37

PC Close Date & Time

24 AUG 2020 13:07

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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

25 AUG 2020 09:22

PC Open Date & Time

24 AUG 2020 14:02

PC Close Date & Time

25 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

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

26 AUG 2020 05:29

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

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

27 AUG 2020 00:26

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

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

27 AUG 2020 20:04

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

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

29 AUG 2020 07:55

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

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

30 AUG 2020 08:26

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

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

30 AUG 2020 22:22

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 10:52
PC Open Date & Time	24 AUG 2020 10:37
PC Close Date & Time	24 AUG 2020 13:07

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 09:22
PC Open Date & Time	24 AUG 2020 14:02
PC Close Date & Time	25 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

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 ☒

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 05:30
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

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 ☒

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

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 ☒

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 20:04
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

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 ☒

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 07:55
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

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 ☒

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 08:28
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

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 ☒

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 22:22
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3022291

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

Was Contact Attempted?

Yes ☒

No ☐

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

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022291

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

Was Contact Attempted?

Yes ☒

No ☐

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

07 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022291

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

Was Contact Attempted?

Yes ☒

No ☐

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

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022291

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

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)	28 SEP 2020
Time of assessment (00:00-23:59)	12:46 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 12:46
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

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)	28 SEP 2020
Time of assessment (00:00-23:59)	15:04 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 15:04
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3022291

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3022291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	28 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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)	28 SEP 2020
What was the treatment time? (00:00-23:59)	14:34 (24 HR)
Treatment Date and Time (derived)	28 SEP 2020 14:34
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3022291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	28 SEP 2020
Collection time (<i>00:00-23:59</i>)	13:02 (24 HR)
Collection date and time (derived)	28 SEP 2020 13:02

US3022291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:40:41

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:24	28 SEP 2020 13:24
Nasopharyngeal Swab 2	No		

US3022291

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

28 SEP 2020 15:02

PC Open Date & Time

28 SEP 2020 14:54

PC Close Date & Time

28 SEP 2020 17:24

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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 96.6 °F

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

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

PC Time Stamp	29 SEP 2020 08:18
PC Open Date & Time	28 SEP 2020 18:19
PC Close Date & Time	29 SEP 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

30 SEP 2020 00:01

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 00:00

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 12:13

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

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

97.3 °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

03 OCT 2020 19:03

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

05 OCT 2020 09:40

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 15:03

PC Open Date & Time

28 SEP 2020 14:54

PC Close Date & Time

28 SEP 2020 17:24

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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

29 SEP 2020 08:18

PC Open Date & Time

28 SEP 2020 18:19

PC Close Date & Time

29 SEP 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

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

30 SEP 2020 00:02

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

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

02 OCT 2020 00:00

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

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

02 OCT 2020 12:13

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

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

03 OCT 2020 19:04

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

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

05 OCT 2020 09:41

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 15:04
PC Open Date & Time	28 SEP 2020 14:54
PC Close Date & Time	28 SEP 2020 17:24

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 08:19
PC Open Date & Time	28 SEP 2020 18:19
PC Close Date & Time	29 SEP 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

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 ☒

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 00:13
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

		Yes <input type="checkbox"/>
<hr/>		
PC Time stamp		
<hr/>		
PC Open Date & Time		30 SEP 2020 12:00
<hr/>		
PC Close Date & Time		01 OCT 2020 11:59
<hr/>		

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

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 ☒

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 00:00
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

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 ☒

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:15
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

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 ☒

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 19:04
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

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 ☒

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 09:41
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3022291

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

Was Contact Attempted?

Yes ☒

No ☐

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

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022291

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

Was Contact Attempted?

Yes ☒

No ☐

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

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022291

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

Was Contact Attempted?

Yes ☒

No ☐

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

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022291

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	08:24 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 08:24
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	64 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022291

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 2020

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

US3022291

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	23 OCT 2020
Collection time (<i>00:00-23:59</i>)	08:39 (24 HR)
Collection date and time (derived)	23 OCT 2020 08:39

US3022291

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 OCT 2020 00:47:55

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

31 OCT 2020 00:02:11

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 NOV 2020 00:02:25

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2020 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

01 NOV 2020 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

08 NOV 2020 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

15 NOV 2020 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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="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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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="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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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="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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 159

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

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

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

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

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

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

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 166

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

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

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

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

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

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

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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="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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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="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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 236

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAY 2021 00:01
Patient Cloud Close Date & Time	16 MAY 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	20 JUN 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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="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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	27 JUN 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	01 AUG 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
Patient Cloud Close Date & Time	22 AUG 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
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Patient Cloud Open Date & Time	25 AUG 2021 00:01
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Patient Cloud Close Date & Time	29 AUG 2021 23:59
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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
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Patient Cloud Close Date & Time	19 SEP 2021 23:59
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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	26 SEP 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	14 NOV 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	21 NOV 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	12 DEC 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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="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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	26 DEC 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 <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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01
Patient Cloud Close Date & Time	03 APR 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	24 APR 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	10 JUL 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	28 AUG 2022 23:59
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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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"/>

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	11 SEP 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	25 SEP 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	09 OCT 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3022291

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3022291

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 08:40:41

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3022291

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 08:40:41

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

AEID	USA-US051-2020-MRNA-1273-P30 1000013
Adverse event	WORSENING OF RIGHT KNEE ARTHRITIS
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)	09 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)	12 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 type="radio"/> Grade 4 <input checked="" 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)	09 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	12 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)

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US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PRE-PLANNED SURGERY FOR WORSENING FOR RIGHT KNEE ARTHRITIS THAT STARED IN UN/UNK/2019
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

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:40:41

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

Yes ☒

No ☐

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

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

Name of Medication	DICLOFENAC
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	RIGHT KNEE ARTHRITIS
Dose per administration	75-200
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 checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

Name of Medication	CELECOXIB
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	RIGHT KNEE ARTHRITIS
Dose per administration	100
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 checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

	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 JAN 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

Name of Medication	ALQUIST
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	WORSENING RIGHT KNEE ARTHRITIS
Dose per administration	2.5
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input checked="" type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

	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)	09 NOV 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) <hr/>		
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"/>

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

Name of Medication	OXYCODONE/ACETAMINOPHE N
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	WORSENING RIGHT KNEE ARTHRITIS
Dose per administration	10/325
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"/>

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	09 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3022291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:40:41

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3022291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 08:40:41

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
09 NOV 2020	RIGHT KNEE REPLACEMENT	Adverse Event	

US3022291

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:40:41

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

US3022291

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

SAEID	USA-US051-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:40:41

SAEID	USA-US051-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	24/NOV/2020 01:00
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

US3022291 (Prod: Meridian Clinical Research)

US3022291

Form: Participant Creation

Generated On: 26 Nov 2020 08:40:41

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3022291'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Aug 2020 12:19:27

US3022291

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:24:49

US3022291

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Aug 2020 12:19:28

US3022291

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:24:49

US3022291

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	24 Aug 2020 19:24:49

US3022291

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1975'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Aug 2020 12:19:29

US3022291

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Age](#)

Audit	User	Time (GMT)
User entered '45'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:26:02

US3022291

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	24 Aug 2020 19:26:02

US3022291

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '45'	System	24 Aug 2020 14:48:39

US3022291

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:26:02

US3022291

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Reported (NOT REPORTED)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:26:02

US3022291

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[White](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:26:02

US3022291

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Black](#)

Audit	User	Time (GMT)
User entered 'I'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:26:02

US3022291

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:26:02

US3022291

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:26:02

US3022291

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:26:02

US3022291

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:26:02

US3022291

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:26:02

US3022291

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:26:02

US3022291

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:26:02

US3022291

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Chevon Roberts (b) (4) (b) (4)	24 Aug 2020 14:48:39

(b)

US3022291

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	24 Aug 2020 14:48:39

US3022291

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '2020'	System	24 Aug 2020 14:48:39

US3022291

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Chevon Roberts (b) (4) (b) (4)	24 Aug 2020 14:48:39

US3022291

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Chevon Roberts (b) (4) (b) (4)	24 Aug 2020 14:48:39

US3022291

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	Chevon Roberts (b) (4) (b) (4)	24 Aug 2020 14:48:39

US3022291

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Chevon Roberts (b) (4) (b) (4)	24 Aug 2020 14:48:39

US3022291

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Chevon Roberts (b) (4) (b) (4)	24 Aug 2020 14:48:39

US3022291

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Aug 2020 12:19:28

US3022291

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Aug 2020 14:48:42

US3022291

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Chevon Roberts (b) (4) (b) (4)	24 Aug 2020 14:48:42

US3022291

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 08:40:41

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:26:24

US3022291

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 21:46:16
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' answered with 'NO MEDS TAKEN FOR THIS ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 20:42:09
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 08:24:41
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:27:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:27:43
Data point term sent to Coder	System	24 Aug 2020 19:26:39
User entered 'Asthma'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:26:37

US3022291

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'un UNK 1980'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:26:37

US3022291

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:26:37

US3022291

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:26:37

US3022291

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:26:37

US3022291

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:26:37

US3022291

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	24 Aug 2020 19:26:37

US3022291

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '1980'	System	24 Aug 2020 19:26:37

US3022291

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 19:26:37

US3022291

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 19:26:37

US3022291

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:40:41

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:29:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:29:38
Data point term sent to Coder	System	24 Aug 2020 19:28:46
User entered 'right knee arthritis'	Stella Yoon (b) (4)	24 Aug 2020 19:28:39
	(b) (4)	

US3022291

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:28:39

US3022291

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:40:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:28:39

US3022291

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:40:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:28:39

US3022291

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:28:39

US3022291

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:40:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:28:39

US3022291

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	24 Aug 2020 19:28:39

US3022291

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '2019'	System	24 Aug 2020 19:28:39

US3022291

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 19:28:39

US3022291

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 19:28:39

US3022291

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:40:41

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:30:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:30:35
Data point term sent to Coder	System	24 Aug 2020 19:29:47
User entered 'Hypertension'	Stella Yoon (b) (4)	24 Aug 2020 19:28:54
	(b) (4)	

US3022291

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:28:54

US3022291

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:40:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:28:54

US3022291

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:40:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:28:54

US3022291

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:28:54

US3022291

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:40:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:28:54

US3022291

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	24 Aug 2020 19:28:54

US3022291

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '2005'	System	24 Aug 2020 19:28:54

US3022291

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 19:28:54

US3022291

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 19:28:54

US3022291

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:40:41

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:30:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:30:37
Data point term sent to Coder	System	24 Aug 2020 19:29:48
User entered 'tubal ligation'	Stella Yoon (b) (4)	24 Aug 2020 19:29:13
	(b) (4)	

US3022291

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'un UNK 2006'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:29:13

US3022291

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:40:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:29:13

US3022291

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:40:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:29:13

US3022291

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'un UNK 2006'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:29:13

US3022291

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:40:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:29:13

US3022291

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	24 Aug 2020 19:29:13

US3022291

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '2006'	System	24 Aug 2020 19:29:13

US3022291

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	24 Aug 2020 19:29:13

US3022291

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '2006'	System	24 Aug 2020 19:29:13

US3022291

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:40:41

Condition

Audit	User	Time (GMT)
User closed query 'Per CDM: Thank you for confirming procedure was for weight loss. Please consider adding associated condition of obesity on Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 13:06:36
Query 'Per CDM: Thank you for confirming procedure was for weight loss. Please consider adding associated condition of obesity on Med History eCRF.' answered with 'updated' (Site from DM).	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 19:07:52
User opened query 'Per CDM: Thank you for confirming procedure was for weight loss. Please consider adding associated condition of obesity on Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 14:22:24
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 14:22:24
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate.' answered with 'NO OTHER CONDITON LED TO THIS. DID THIS FOR WEIGHT LOSS' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 20:44:08
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 08:25:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric bypass, LLT: Gastric bypass - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:30:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 19:30:37
Data point term sent to Coder	System	24 Aug 2020 19:29:48
User entered 'Gastric Bypass'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:29:32

US3022291

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'un UNK 2008'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:29:32

US3022291

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:40:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:29:32

US3022291

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:40:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:29:32

US3022291

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'un UNK 2008'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:29:32

US3022291

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:40:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:29:32

US3022291

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	24 Aug 2020 19:29:32

US3022291

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '2008'	System	24 Aug 2020 19:29:32

US3022291

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	24 Aug 2020 19:29:32

US3022291

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '2008'	System	24 Aug 2020 19:29:32

US3022291

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:40:41

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric ulcer surgery, LLT: Gastric ulcer surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 21:09:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 21:09:41
Data point term sent to Coder	System	17 Sep 2020 21:08:03
User closed query 'DM-Coding: Please clarify the type/location of ulcer. Please update the reported term.' (Site from System).	System	17 Sep 2020 21:07:17
Query 'DM-Coding: Please clarify the type/location of ulcer. Please update the reported term.' answered with 'updated' (Site from System).	Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:07:17
User entered 'stomach ULCER SURGERY' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:07:12
User opened query 'DM-Coding: Please clarify the type/location of ulcer. Please update the reported term.' (Site from System).	Coder Import (b) (4) (b) (4)	09 Sep 2020 06:26:33
Data point term sent to Coder	System	24 Aug 2020 19:29:50
User entered 'Ulcer surgery'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:29:47

US3022291

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:29:47

US3022291

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:40:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:29:47

US3022291

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:40:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:29:47

US3022291

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:29:47

US3022291

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:40:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:29:47

US3022291

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	24 Aug 2020 19:29:47

US3022291

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '2016'	System	24 Aug 2020 19:29:47

US3022291

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	24 Aug 2020 19:29:47

US3022291

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '2016'	System	24 Aug 2020 19:29:47

US3022291

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:40:41

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Gastric ulcers and perforation, PT: Gastric ulcer, LLT: Stomach ulcer - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:31:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:31:40
Data point term sent to Coder	System	24 Aug 2020 19:30:51
User entered 'Stomach Ulcer'	Stella Yoon (b) (4)	24 Aug 2020 19:30:05
	(b) (4)	

US3022291

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:30:05

US3022291

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:40:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:30:05

US3022291

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:40:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:30:05

US3022291

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:30:05

US3022291

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:40:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:30:05

US3022291

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	24 Aug 2020 19:30:05

US3022291

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '2016'	System	24 Aug 2020 19:30:05

US3022291

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	24 Aug 2020 19:30:05

US3022291

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '2016'	System	24 Aug 2020 19:30:05

US3022291

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:40:41

[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)	01 Oct 2020 19:09:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 19:09:21
Data point term sent to Coder	System	01 Oct 2020 19:07:43
User entered 'obesity'	Stella Yoon (b) (4)	01 Oct 2020 19:07:41
	(b) (4)	

US3022291

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered (b) (6) 1975'	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 19:07:41

US3022291

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:40:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 19:07:41

US3022291

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:40:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 19:07:41

US3022291

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 19:07:41

US3022291

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:40:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	01 Oct 2020 19:07:41

US3022291

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered (b) (6) 1975'	System	01 Oct 2020 19:07:41

US3022291

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '1975'	System	01 Oct 2020 19:07:41

US3022291

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:07:41

US3022291

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:07:41

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:31:27

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:31:27

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '08:09'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:31:27

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 08:09'	System	24 Aug 2020 19:31:27

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '171' cm	Stella Yoon (b) (4)	24 Aug 2020 19:31:27
DataPoint set to visible.	(b) (4) System	24 Aug 2020 14:48:42

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '118.2' kg	Stella Yoon (b) (4)	24 Aug 2020 19:31:27
DataPoint set to visible.	(b) (4) System	24 Aug 2020 14:48:42

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
Amendment Manager: User entered '40.42269'	System	17 Sep 2020 00:20:43
User entered '40.4'	System	24 Aug 2020 19:31:27
DataPoint set to visible.	System	24 Aug 2020 14:48:42

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	24 Aug 2020 19:31:27
DataPoint set to visible.	System	24 Aug 2020 14:48:42

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:02:29
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 14:59:33
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:59:20
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:04:06
User entered '36.5' C	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:31:27

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:59:20
User entered 'Oral (Oral)'	Stella Yoon (b) (4)	24 Aug 2020 19:31:27

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:31:27

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:59:20
User entered '76'	Stella Yoon (b) (4)	24 Aug 2020 19:31:27

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Aug 2020 19:31:27

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:59:20
User entered '13'	Stella Yoon (b) (4)	24 Aug 2020 19:31:27

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Aug 2020 19:31:27

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:59:20
User entered '122'	Stella Yoon (b) (4)	24 Aug 2020 19:31:27

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 19:31:27

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:59:20
User entered '84'	Stella Yoon (b) (4)	24 Aug 2020 19:31:27

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 19:31:27

US3022291

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:31:36

US3022291

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:31:36

US3022291

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:40:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:31:43

US3022291

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:40:41

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:31:43

US3022291

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:31:43

US3022291

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:31:43

US3022291

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:31:43

US3022291

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:40:41

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:31:43

US3022291

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:31:43

US3022291

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:40:41

Date of last menstruation unknown

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:31:43

US3022291

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:31

US3022291

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:31

US3022291

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Serum (SERUM)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:31

US3022291

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:31

US3022291

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:31

US3022291

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:31

US3022291

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:31

US3022291

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 19:32:31

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

Other

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '1'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

[Other](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Stella Yoon (b) (4)	24 Aug 2020 19:32:21
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

[Specify](#)

Audit	User	Time (GMT)
User closed query 'Other specified is provided for Location and Living Circumstances Risk, but OTHER is not selected for Location and Living Circumstances Risk. Please reconcile.' (Site from System).	System	24 Aug 2020 19:32:21
User opened query 'Other specified is provided for Location and Living Circumstances Risk, but OTHER is not selected for Location and Living Circumstances Risk. Please reconcile.' (Site from System).	System	24 Aug 2020 19:32:10
User entered 'lives in community with ongoing person to person transmission'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:40

US3022291

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:40

US3022291

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:40

US3022291

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	24 Aug 2020 19:32:40

US3022291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	24 Aug 2020 13:19:58

US3022291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:41

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '144809'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	24 Aug 2020 13:19:58

US3022291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Aug 2020 13:19:58

US3022291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:57

US3022291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:57

US3022291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:57

US3022291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:41

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:57

US3022291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:41

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:57

US3022291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 12:44:36
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 18:39:50
User entered 'No (N)'	Morgan Deal (b) (4)	12 Nov 2020 18:39:44
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 19:02:31
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:39:38
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:24:28

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:40:41

Height

Audit	User	Time (GMT)
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:53:49
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 14:57:32
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:57:04
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:39:16
User entered '171' cm	Stella Yoon (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:40:41

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:57:04
User entered '118.2' kg	Stella Yoon (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:40:41

Height

Audit	User	Time (GMT)
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:53:49
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 14:57:32
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:57:04
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:39:16
User entered '171' cm	Stella Yoon (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:40:41

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:57:04
User entered '118.2' kg	Stella Yoon (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '08:09'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 08:09'	System	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.5' C	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '13'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '122'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '84'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:40:41

Height

Audit	User	Time (GMT)
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:53:49
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 14:57:32
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:57:04
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:39:16
User entered '171' cm	Stella Yoon (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:40:41

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:57:04
User entered '118.2' kg	Stella Yoon (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '10:50'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 10:50'	System	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.5' C	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '14'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '124'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '82'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:11

US3022291

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:11

US3022291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Screening and V1D1 have occurred on the same day and data reported on this page is to be recorded on Pregnancy test form at Screening. Please consider to mark responses for "Was the pregnancy test performed?" as No and make the rest of the data points on this page blank. Refer to page 24 of CCGs for more details. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 14:01:30
Query 'Per CDM: Screening and V1D1 have occurred on the same day and data reported on this page is to be recorded on Pregnancy test form at Screening. Please consider to mark responses for "Was the pregnancy test performed?" as No and make the rest of the data points on this page blank. Refer to page 24 of CCGs for more details. Thank you.' answered with 'fixed' (Site from DM).	Stella Yoon (b) (4)	17 Sep 2020 21:06:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 21:06:28
User opened query 'Per CDM: Screening and V1D1 have occurred on the same day and data reported on this page is to be recorded on Pregnancy test form at Screening. Please consider to mark responses for "Was the pregnancy test performed?" as No and make the rest of the data points on this page blank. Refer to page 24 of CCGs for more details. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 11:05:32
User entered 'Yes (Y)'	Stella Yoon (b) (4)	24 Aug 2020 19:34:19

US3022291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Stella Yoon (b) (4)	17 Sep 2020 21:06:28
User entered '24 Aug 2020'	Stella Yoon (b) (4)	24 Aug 2020 19:34:19

US3022291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

[Test performed](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Stella Yoon (b) (4)	17 Sep 2020 21:06:28
User entered 'Urine (URINE)'	Stella Yoon (b) (4)	24 Aug 2020 19:34:19

US3022291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

[Result](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Stella Yoon (b) (4)	17 Sep 2020 21:06:28
User entered 'Negative (NEGATIVE)'	Stella Yoon (b) (4)	24 Aug 2020 19:34:19

US3022291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

Was FSH sample collected?

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 10:46:52
Query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". Please update as appropriate. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 19:29:09
User entered 'No (N)' reason for change: Data Entry Error	Morgan Deal (b) (4)	12 Nov 2020 19:29:03
User opened query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 08:44:51
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:19

US3022291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:19

US3022291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:19

US3022291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 19:34:19

US3022291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Chevon Roberts (b) (4) (b) (4)	24 Aug 2020 14:49:01

US3022291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Chevon Roberts (b) (4) (b) (4)	24 Aug 2020 14:49:01

US3022291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	Chevon Roberts (b) (4) (b) (4)	24 Aug 2020 14:49:01

US3022291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 14:49:01

US3022291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Chevon Roberts (b) (4) (b) (4)	24 Aug 2020 14:49:01

US3022291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '10:17'	Chevon Roberts (b) (4) (b) (4)	24 Aug 2020 14:49:01

US3022291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 10:17'	System	24 Aug 2020 14:49:01

US3022291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Chevon Roberts (b) (4) (b) (4)	24 Aug 2020 14:49:01

US3022291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	24 Aug 2020 14:49:01

US3022291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 14:49:01

US3022291

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:37

US3022291

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:37

US3022291

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:12'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:37

US3022291

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 09:12'	System	24 Aug 2020 19:34:37

US3022291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:40:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:52

US3022291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:40:41

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:52

US3022291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:40:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:52

US3022291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:40:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '08:50'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:52

US3022291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 08:50'	System	24 Aug 2020 19:34:52

US3022291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:40:41

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:52

US3022291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:40:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:52

US3022291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:40:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:52

US3022291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 19:34:52

US3022291

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:58

US3022291

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:34:58

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:50:52', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '29cc00c7-66c6-4c02-9b48-1d01aecc11f8'	System	24 Aug 2020 14:51:07
User entered 'Yes (Y)'	System	24 Aug 2020 14:51:07

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:50:56', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '29cc00c7-66c6-4c02-9b48-1d01aecc11f8'	System	24 Aug 2020 14:51:07
User entered '97.6'	System	24 Aug 2020 14:51:07

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:51:01', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '29cc00c7-66c6-4c02-9b48-1d01aecc11f8'	System	24 Aug 2020 14:51:07
User entered 'No (N)'	System	24 Aug 2020 14:51:07

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:51:05', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '29cc00c7-66c6-4c02-9b48-1d01aecc11f8'	System	24 Aug 2020 14:51:07
User entered '24 Aug 2020 10:51'	System	24 Aug 2020 14:51:07

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 10:37'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 13:07'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:21:53', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '77a690f0-7d6a-4490-b852-2d784790e98a'	System	25 Aug 2020 13:22:04
User entered 'Yes (Y)'	System	25 Aug 2020 13:22:04

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:21:56', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '77a690f0-7d6a-4490-b852-2d784790e98a'	System	25 Aug 2020 13:22:04
User entered '96.1'	System	25 Aug 2020 13:22:04

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '77a690f0-7d6a-4490-b852-2d784790e98a'	System	25 Aug 2020 13:22:04
User entered 'No (N)'	System	25 Aug 2020 13:22:04

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:03', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '77a690f0-7d6a-4490-b852-2d784790e98a'	System	25 Aug 2020 13:22:04
User entered '25 Aug 2020 09:22'	System	25 Aug 2020 13:22:04

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 14:02'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 2'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:09', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7e5d8d8f-7ad8-43df-919d-7938ce35fd4a'	System	26 Aug 2020 09:29:25
User entered 'Yes (Y)'	System	26 Aug 2020 09:29:25

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:14', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7e5d8d8f-7ad8-43df-919d-7938ce35fd4a'	System	26 Aug 2020 09:29:25
User entered '97.2'	System	26 Aug 2020 09:29:25

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:18', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7e5d8d8f-7ad8-43df-919d-7938ce35fd4a'	System	26 Aug 2020 09:29:25
User entered 'No (N)'	System	26 Aug 2020 09:29:25

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:24', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7e5d8d8f-7ad8-43df-919d-7938ce35fd4a'	System	26 Aug 2020 09:29:25
User entered '26 Aug 2020 05:29'	System	26 Aug 2020 09:29:25

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 3'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:25:37', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'a41e7d1e-f1da-4e8e-85d2-bbadb875f7fc'	System	27 Aug 2020 04:25:48
User entered 'Yes (Y)'	System	27 Aug 2020 04:25:48

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:25:40', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'a41e7d1e-f1da-4e8e-85d2-bbadb875f7fc' User entered '97.2'	System	27 Aug 2020 04:25:48

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:25:43', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'a41e7d1e-f1da-4e8e-85d2-bbadb875f7fc'	System	27 Aug 2020 04:25:48
User entered 'No (N)'	System	27 Aug 2020 04:25:48

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:25:45', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'a41e7d1e-f1da-4e8e-85d2-bbadb875f7fc' User entered '27 Aug 2020 00:25'	System	27 Aug 2020 04:25:48

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 4'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:02:58', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3aa00341-065e-4781-b1f0-7f9157be7484'	System	28 Aug 2020 00:04:05
User entered 'Yes (Y)'	System	28 Aug 2020 00:04:05

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:03:57', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3aa00341-065e-4781-b1f0-7f9157be7484'	System	28 Aug 2020 00:04:05
User entered '96.4'	System	28 Aug 2020 00:04:05

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3aa00341-065e-4781-b1f0-7f9157be7484'	System	28 Aug 2020 00:04:05
User entered 'No (N)'	System	28 Aug 2020 00:04:05

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:03', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3aa00341-065e-4781-b1f0-7f9157be7484'	System	28 Aug 2020 00:04:05
User entered '27 Aug 2020 20:04'	System	28 Aug 2020 00:04:05

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 5'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:20', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '97bd78a0-3206-4313-aa60-df5ad8b263fd'	System	29 Aug 2020 11:55:35
User entered 'Yes (Y)'	System	29 Aug 2020 11:55:35

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:24', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '97bd78a0-3206-4313-aa60-df5ad8b263fd' User entered '97.3'	System	29 Aug 2020 11:55:35

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:27', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '97bd78a0-3206-4313-aa60-df5ad8b263fd'	System	29 Aug 2020 11:55:35
User entered 'No (N)'	System	29 Aug 2020 11:55:35

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:29', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '97bd78a0-3206-4313-aa60-df5ad8b263fd'	System	29 Aug 2020 11:55:35
User entered '29 Aug 2020 07:55'	System	29 Aug 2020 11:55:35

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 6'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:23', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '73532dae-2e7c-44f1-88e6-2a404523158b'	System	30 Aug 2020 12:26:40
User entered 'Yes (Y)'	System	30 Aug 2020 12:26:40

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:33', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '73532dae-2e7c-44f1-88e6-2a404523158b'	System	30 Aug 2020 12:26:40
User entered '97.0'	System	30 Aug 2020 12:26:40

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:36', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '73532dae-2e7c-44f1-88e6-2a404523158b'	System	30 Aug 2020 12:26:40
User entered 'No (N)'	System	30 Aug 2020 12:26:40

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:38', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '73532dae-2e7c-44f1-88e6-2a404523158b'	System	30 Aug 2020 12:26:40
User entered '30 Aug 2020 08:26'	System	30 Aug 2020 12:26:40

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 7'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:21:59', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '44877878-ef25-463d-8554-7eea0ba3bfd4'	System	31 Aug 2020 02:22:17
User entered 'Yes (Y)'	System	31 Aug 2020 02:22:17

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:02', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '44877878-ef25-463d-8554-7eea0ba3bfd4'	System	31 Aug 2020 02:22:17
User entered '94.3'	System	31 Aug 2020 02:22:17

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:05', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '44877878-ef25-463d-8554-7eea0ba3bfd4'	System	31 Aug 2020 02:22:17
User entered 'No (N)'	System	31 Aug 2020 02:22:17

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:15', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '44877878-ef25-463d-8554-7eea0ba3bfd4'	System	31 Aug 2020 02:22:17
User entered '30 Aug 2020 22:22'	System	31 Aug 2020 02:22:17

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:51:59', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '19887c33-c3ea-4fe4-af1f-1a316ee5a29c'	System	24 Aug 2020 14:52:26
User entered 'None (1)'	System	24 Aug 2020 14:52:26

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:13', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '19887c33-c3ea-4fe4-af1f-1a316ee5a29c'	System	24 Aug 2020 14:52:26
User entered 'No (N)'	System	24 Aug 2020 14:52:26

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:16', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '19887c33-c3ea-4fe4-af1f-1a316ee5a29c'	System	24 Aug 2020 14:52:26
User entered 'No (N)'	System	24 Aug 2020 14:52:26

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:18', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '19887c33-c3ea-4fe4-af1f-1a316ee5a29c'	System	24 Aug 2020 14:52:26
User entered 'None (1)'	System	24 Aug 2020 14:52:26

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:21', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '19887c33-c3ea-4fe4-af1f-1a316ee5a29c'	System	24 Aug 2020 14:52:26
User entered '24 Aug 2020 10:52'	System	24 Aug 2020 14:52:26

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 10:37'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 13:07'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:08', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '86545e39-6414-4021-a35e-910de966b38e'	System	25 Aug 2020 13:22:27
User entered 'None (1)'	System	25 Aug 2020 13:22:27

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:14', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '86545e39-6414-4021-a35e-910de966b38e'	System	25 Aug 2020 13:22:27
User entered 'No (N)'	System	25 Aug 2020 13:22:27

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:16', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '86545e39-6414-4021-a35e-910de966b38e'	System	25 Aug 2020 13:22:27
User entered 'No (N)'	System	25 Aug 2020 13:22:27

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:22', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '86545e39-6414-4021-a35e-910de966b38e'	System	25 Aug 2020 13:22:27
User entered 'None (1)'	System	25 Aug 2020 13:22:27

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:25', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '86545e39-6414-4021-a35e-910de966b38e' User entered '25 Aug 2020 09:22'	System	25 Aug 2020 13:22:27
	System	25 Aug 2020 13:22:27

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 14:02'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 2'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:34', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e1b4546e-40b8-4df9-9cec-f023e64b591b'	System	26 Aug 2020 09:29:46
User entered 'None (1)'	System	26 Aug 2020 09:29:46

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:37', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e1b4546e-40b8-4df9-9cec-f023e64b591b'	System	26 Aug 2020 09:29:46
User entered 'No (N)'	System	26 Aug 2020 09:29:46

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:40', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e1b4546e-40b8-4df9-9cec-f023e64b591b'	System	26 Aug 2020 09:29:46
User entered 'No (N)'	System	26 Aug 2020 09:29:46

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:43', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e1b4546e-40b8-4df9-9cec-f023e64b591b'	System	26 Aug 2020 09:29:46
User entered 'None (1)'	System	26 Aug 2020 09:29:46

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:45', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e1b4546e-40b8-4df9-9cec-f023e64b591b' User entered '26 Aug 2020 05:29'	System	26 Aug 2020 09:29:46
	System	26 Aug 2020 09:29:46

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 3'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:25:50', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc21f545-edb4-4a42-9864-18d1b8bc57d9'	System	27 Aug 2020 04:26:02
User entered 'None (1)'	System	27 Aug 2020 04:26:02

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:25:52', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc21f545-edb4-4a42-9864-18d1b8bc57d9'	System	27 Aug 2020 04:26:02
User entered 'No (N)'	System	27 Aug 2020 04:26:02

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:25:55', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc21f545-edb4-4a42-9864-18d1b8bc57d9'	System	27 Aug 2020 04:26:02
User entered 'No (N)'	System	27 Aug 2020 04:26:02

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:25:57', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc21f545-edb4-4a42-9864-18d1b8bc57d9'	System	27 Aug 2020 04:26:02
User entered 'None (1)'	System	27 Aug 2020 04:26:02

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:26:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc21f545-edb4-4a42-9864-18d1b8bc57d9'	System	27 Aug 2020 04:26:02
User entered '27 Aug 2020 00:26'	System	27 Aug 2020 04:26:02

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 4'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:14', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'b4b2b663-2fec-4825-ab37-947fe9edc4ce'	System	28 Aug 2020 00:04:31
User entered 'None (1)'	System	28 Aug 2020 00:04:31

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:17', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'b4b2b663-2fec-4825-ab37-947fe9edc4ce'	System	28 Aug 2020 00:04:31
User entered 'No (N)'	System	28 Aug 2020 00:04:31

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:20', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'b4b2b663-2fec-4825-ab37-947fe9edc4ce'	System	28 Aug 2020 00:04:31
User entered 'No (N)'	System	28 Aug 2020 00:04:31

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:24', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'b4b2b663-2fec-4825-ab37-947fe9edc4ce'	System	28 Aug 2020 00:04:31
User entered 'None (1)'	System	28 Aug 2020 00:04:31

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:27', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'b4b2b663-2fec-4825-ab37-947fe9edc4ce'	System	28 Aug 2020 00:04:31
User entered '27 Aug 2020 20:04'	System	28 Aug 2020 00:04:31

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 5'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:05', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '4cc08220-39cc-4aaf-be3d-806c0daf77d5'	System	29 Aug 2020 11:55:18
User entered 'None (1)'	System	29 Aug 2020 11:55:18

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:08', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '4cc08220-39cc-4aaf-be3d-806c0daf77d5'	System	29 Aug 2020 11:55:18
User entered 'No (N)'	System	29 Aug 2020 11:55:18

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:10', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '4cc08220-39cc-4aaf-be3d-806c0daf77d5'	System	29 Aug 2020 11:55:18
User entered 'No (N)'	System	29 Aug 2020 11:55:18

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:13', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '4cc08220-39cc-4aaf-be3d-806c0daf77d5'	System	29 Aug 2020 11:55:18
User entered 'None (1)'	System	29 Aug 2020 11:55:18

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:15', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '4cc08220-39cc-4aaf-be3d-806c0daf77d5'	System	29 Aug 2020 11:55:18
User entered '29 Aug 2020 07:55'	System	29 Aug 2020 11:55:18

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 6'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:42', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '1844fa4d-f8ac-4f4d-b103-3140743dd065'	System	30 Aug 2020 12:26:54
User entered 'None (1)'	System	30 Aug 2020 12:26:54

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:45', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '1844fa4d-f8ac-4f4d-b103-3140743dd065'	System	30 Aug 2020 12:26:54
User entered 'No (N)'	System	30 Aug 2020 12:26:54

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:48', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '1844fa4d-f8ac-4f4d-b103-3140743dd065'	System	30 Aug 2020 12:26:54
User entered 'No (N)'	System	30 Aug 2020 12:26:54

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:50', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '1844fa4d-f8ac-4f4d-b103-3140743dd065'	System	30 Aug 2020 12:26:54
User entered 'None (1)'	System	30 Aug 2020 12:26:54

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:52', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '1844fa4d-f8ac-4f4d-b103-3140743dd065'	System	30 Aug 2020 12:26:54
User entered '30 Aug 2020 08:26'	System	30 Aug 2020 12:26:54

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 7'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:19', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ffb7b272-b42e-4418-86d5-2cc32afeeda3'	System	31 Aug 2020 02:22:33
User entered 'None (1)'	System	31 Aug 2020 02:22:33

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:23', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ffb7b272-b42e-4418-86d5-2cc32afeeda3'	System	31 Aug 2020 02:22:33
User entered 'No (N)'	System	31 Aug 2020 02:22:33

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:26', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ffb7b272-b42e-4418-86d5-2cc32afeeda3'	System	31 Aug 2020 02:22:33
User entered 'No (N)'	System	31 Aug 2020 02:22:33

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:28', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ffb7b272-b42e-4418-86d5-2cc32afeeda3'	System	31 Aug 2020 02:22:33
User entered 'None (1)'	System	31 Aug 2020 02:22:33

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:30', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ffb7b272-b42e-4418-86d5-2cc32afeeda3'	System	31 Aug 2020 02:22:33
User entered '30 Aug 2020 22:22'	System	31 Aug 2020 02:22:33

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:26', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0fe09150-519e-404c-88b0-4e303b10ea18'	System	24 Aug 2020 14:52:47
User entered 'None (0)'	System	24 Aug 2020 14:52:47

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:29', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0fe09150-519e-404c-88b0-4e303b10ea18'	System	24 Aug 2020 14:52:47
User entered 'None (0)'	System	24 Aug 2020 14:52:47

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:32', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0fe09150-519e-404c-88b0-4e303b10ea18'	System	24 Aug 2020 14:52:47
User entered 'None (0)'	System	24 Aug 2020 14:52:47

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:34', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0fe09150-519e-404c-88b0-4e303b10ea18'	System	24 Aug 2020 14:52:47
User entered 'None (0)'	System	24 Aug 2020 14:52:47

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:36', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0fe09150-519e-404c-88b0-4e303b10ea18'	System	24 Aug 2020 14:52:47
User entered 'None (0)'	System	24 Aug 2020 14:52:47

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:39', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0fe09150-519e-404c-88b0-4e303b10ea18'	System	24 Aug 2020 14:52:47
User entered 'None (0)'	System	24 Aug 2020 14:52:47

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:44', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0fe09150-519e-404c-88b0-4e303b10ea18'	System	24 Aug 2020 14:52:47
User entered 'No (N)'	System	24 Aug 2020 14:52:47

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:46', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0fe09150-519e-404c-88b0-4e303b10ea18'	System	24 Aug 2020 14:52:47
User entered '24 Aug 2020 10:52'	System	24 Aug 2020 14:52:47

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 10:37'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 13:07'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:29', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fb099950-be14-4d83-a099-a7543166eb18'	System	25 Aug 2020 13:22:52
User entered 'None (0)'	System	25 Aug 2020 13:22:52

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:31', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fb099950-be14-4d83-a099-a7543166eb18'	System	25 Aug 2020 13:22:52
User entered 'None (0)'	System	25 Aug 2020 13:22:52

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:33', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fb099950-be14-4d83-a099-a7543166eb18'	System	25 Aug 2020 13:22:52
User entered 'None (0)'	System	25 Aug 2020 13:22:52

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:35', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fb099950-be14-4d83-a099-a7543166eb18'	System	25 Aug 2020 13:22:52
User entered 'None (0)'	System	25 Aug 2020 13:22:52

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:37', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fb099950-be14-4d83-a099-a7543166eb18'	System	25 Aug 2020 13:22:52
User entered 'None (0)'	System	25 Aug 2020 13:22:52

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:39', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fb099950-be14-4d83-a099-a7543166eb18'	System	25 Aug 2020 13:22:52
User entered 'None (0)'	System	25 Aug 2020 13:22:52

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:45', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fb099950-be14-4d83-a099-a7543166eb18'	System	25 Aug 2020 13:22:52
User entered 'No (N)'	System	25 Aug 2020 13:22:52

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:47', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fb099950-be14-4d83-a099-a7543166eb18'	System	25 Aug 2020 13:22:52
User entered '25 Aug 2020 09:22'	System	25 Aug 2020 13:22:52

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 14:02'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 2'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:49', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '35a90924-c4bd-46c4-82e8-7238d1dc2c78'	System	26 Aug 2020 09:30:06
User entered 'None (0)'	System	26 Aug 2020 09:30:06

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:51', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '35a90924-c4bd-46c4-82e8-7238d1dc2c78'	System	26 Aug 2020 09:30:06
User entered 'None (0)'	System	26 Aug 2020 09:30:06

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:53', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '35a90924-c4bd-46c4-82e8-7238d1dc2c78'	System	26 Aug 2020 09:30:06
User entered 'None (0)'	System	26 Aug 2020 09:30:06

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:55', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '35a90924-c4bd-46c4-82e8-7238d1dc2c78'	System	26 Aug 2020 09:30:06
User entered 'None (0)'	System	26 Aug 2020 09:30:06

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:58', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '35a90924-c4bd-46c4-82e8-7238d1dc2c78'	System	26 Aug 2020 09:30:06
User entered 'None (0)'	System	26 Aug 2020 09:30:06

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:30:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '35a90924-c4bd-46c4-82e8-7238d1dc2c78'	System	26 Aug 2020 09:30:06
User entered 'None (0)'	System	26 Aug 2020 09:30:06

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:30:03', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '35a90924-c4bd-46c4-82e8-7238d1dc2c78'	System	26 Aug 2020 09:30:06
User entered 'No (N)'	System	26 Aug 2020 09:30:06

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:30:05', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '35a90924-c4bd-46c4-82e8-7238d1dc2c78'	System	26 Aug 2020 09:30:06
User entered '26 Aug 2020 05:30'	System	26 Aug 2020 09:30:06

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 3'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:26:04', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fff53010-6cec-467e-a650-2f3beb9d15c1'	System	27 Aug 2020 04:26:23
User entered 'None (0)'	System	27 Aug 2020 04:26:23

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:26:07', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fff53010-6cec-467e-a650-2f3beb9d15c1'	System	27 Aug 2020 04:26:23
User entered 'None (0)'	System	27 Aug 2020 04:26:23

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:26:09', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fff53010-6cec-467e-a650-2f3beb9d15c1'	System	27 Aug 2020 04:26:23
User entered 'None (0)'	System	27 Aug 2020 04:26:23

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:26:11', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fff53010-6cec-467e-a650-2f3beb9d15c1'	System	27 Aug 2020 04:26:23
User entered 'None (0)'	System	27 Aug 2020 04:26:23

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:26:13', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fff53010-6cec-467e-a650-2f3beb9d15c1'	System	27 Aug 2020 04:26:23
User entered 'None (0)'	System	27 Aug 2020 04:26:23

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:26:15', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fff53010-6cec-467e-a650-2f3beb9d15c1'	System	27 Aug 2020 04:26:23
User entered 'None (0)'	System	27 Aug 2020 04:26:23

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:26:18', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fff53010-6cec-467e-a650-2f3beb9d15c1'	System	27 Aug 2020 04:26:23
User entered 'No (N)'	System	27 Aug 2020 04:26:23

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:26:20', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fff53010-6cec-467e-a650-2f3beb9d15c1'	System	27 Aug 2020 04:26:23
User entered '27 Aug 2020 00:26'	System	27 Aug 2020 04:26:23

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 4'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:37', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8c5421ae-bf60-4d61-920b-565629d02198'	System	28 Aug 2020 00:04:57
User entered 'None (0)'	System	28 Aug 2020 00:04:57

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:39', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8c5421ae-bf60-4d61-920b-565629d02198'	System	28 Aug 2020 00:04:57
User entered 'None (0)'	System	28 Aug 2020 00:04:57

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:42', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8c5421ae-bf60-4d61-920b-565629d02198'	System	28 Aug 2020 00:04:57
User entered 'None (0)'	System	28 Aug 2020 00:04:57

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:44', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8c5421ae-bf60-4d61-920b-565629d02198'	System	28 Aug 2020 00:04:57
User entered 'None (0)'	System	28 Aug 2020 00:04:57

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:45', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8c5421ae-bf60-4d61-920b-565629d02198'	System	28 Aug 2020 00:04:57
User entered 'None (0)'	System	28 Aug 2020 00:04:57

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:47', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8c5421ae-bf60-4d61-920b-565629d02198'	System	28 Aug 2020 00:04:57
User entered 'None (0)'	System	28 Aug 2020 00:04:57

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:53', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8c5421ae-bf60-4d61-920b-565629d02198'	System	28 Aug 2020 00:04:57
User entered 'No (N)'	System	28 Aug 2020 00:04:57

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:55', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8c5421ae-bf60-4d61-920b-565629d02198'	System	28 Aug 2020 00:04:57
User entered '27 Aug 2020 20:04'	System	28 Aug 2020 00:04:57

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 5'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:32', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '9dfb32ac-6ff0-4ebb-be84-7b1b8898d4e9'	System	29 Aug 2020 11:55:51
User entered 'None (0)'	System	29 Aug 2020 11:55:51

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:35', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '9dfb32ac-6ff0-4ebb-be84-7b1b8898d4e9'	System	29 Aug 2020 11:55:51
User entered 'None (0)'	System	29 Aug 2020 11:55:51

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:37', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '9dfb32ac-6ff0-4ebb-be84-7b1b8898d4e9'	System	29 Aug 2020 11:55:51
User entered 'None (0)'	System	29 Aug 2020 11:55:51

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:39', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '9dfb32ac-6ff0-4ebb-be84-7b1b8898d4e9'	System	29 Aug 2020 11:55:51
User entered 'None (0)'	System	29 Aug 2020 11:55:51

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:41', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '9dfb32ac-6ff0-4ebb-be84-7b1b8898d4e9'	System	29 Aug 2020 11:55:51
User entered 'None (0)'	System	29 Aug 2020 11:55:51

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:42', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '9dfb32ac-6ff0-4ebb-be84-7b1b8898d4e9'	System	29 Aug 2020 11:55:51
User entered 'None (0)'	System	29 Aug 2020 11:55:51

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:46', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '9dfb32ac-6ff0-4ebb-be84-7b1b8898d4e9'	System	29 Aug 2020 11:55:51
User entered 'No (N)'	System	29 Aug 2020 11:55:51

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:48', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '9dfb32ac-6ff0-4ebb-be84-7b1b8898d4e9'	System	29 Aug 2020 11:55:51
User entered '29 Aug 2020 07:55'	System	29 Aug 2020 11:55:51

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 6'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:58', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'bb69faf3-1012-4d04-ab5e-c7c50e82f137'	System	30 Aug 2020 12:28:09
User entered 'None (0)'	System	30 Aug 2020 12:28:09

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:27:02', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'bb69faf3-1012-4d04-ab5e-c7c50e82f137'	System	30 Aug 2020 12:28:09
User entered 'None (0)'	System	30 Aug 2020 12:28:09

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:27:09', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'bb69faf3-1012-4d04-ab5e-c7c50e82f137'	System	30 Aug 2020 12:28:09
User entered 'None (0)'	System	30 Aug 2020 12:28:09

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:27:14', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'bb69faf3-1012-4d04-ab5e-c7c50e82f137'	System	30 Aug 2020 12:28:09
User entered 'None (0)'	System	30 Aug 2020 12:28:09

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:27:48', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'bb69faf3-1012-4d04-ab5e-c7c50e82f137'	System	30 Aug 2020 12:28:09
User entered 'None (0)'	System	30 Aug 2020 12:28:09

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:28:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'bb69faf3-1012-4d04-ab5e-c7c50e82f137'	System	30 Aug 2020 12:28:09
User entered 'None (0)'	System	30 Aug 2020 12:28:09

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:28:02', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'bb69faf3-1012-4d04-ab5e-c7c50e82f137'	System	30 Aug 2020 12:28:09
User entered 'No (N)'	System	30 Aug 2020 12:28:09

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:28:05', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'bb69faf3-1012-4d04-ab5e-c7c50e82f137'	System	30 Aug 2020 12:28:09
User entered '30 Aug 2020 08:28'	System	30 Aug 2020 12:28:09

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 7'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:34', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '47960bdf-95fa-4f86-8733-c28446f2c47d'	System	31 Aug 2020 02:22:54
User entered 'None (0)'	System	31 Aug 2020 02:22:54

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:36', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '47960bdf-95fa-4f86-8733-c28446f2c47d'	System	31 Aug 2020 02:22:54
User entered 'None (0)'	System	31 Aug 2020 02:22:54

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:38', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '47960bdf-95fa-4f86-8733-c28446f2c47d'	System	31 Aug 2020 02:22:54
User entered 'None (0)'	System	31 Aug 2020 02:22:54

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:40', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '47960bdf-95fa-4f86-8733-c28446f2c47d'	System	31 Aug 2020 02:22:54
User entered 'None (0)'	System	31 Aug 2020 02:22:54

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:43', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '47960bdf-95fa-4f86-8733-c28446f2c47d'	System	31 Aug 2020 02:22:54
User entered 'None (0)'	System	31 Aug 2020 02:22:54

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:45', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '47960bdf-95fa-4f86-8733-c28446f2c47d'	System	31 Aug 2020 02:22:54
User entered 'None (0)'	System	31 Aug 2020 02:22:54

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:47', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '47960bdf-95fa-4f86-8733-c28446f2c47d'	System	31 Aug 2020 02:22:54
User entered 'No (N)'	System	31 Aug 2020 02:22:54

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:50', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '47960bdf-95fa-4f86-8733-c28446f2c47d'	System	31 Aug 2020 02:22:54
User entered '30 Aug 2020 22:22'	System	31 Aug 2020 02:22:54

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:13

US3022291

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:13

US3022291

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:13

US3022291

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:13

US3022291

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:17

US3022291

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Sep 2020 19:29:17

US3022291

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:29

US3022291

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '07 Sep 2020'	Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:29

US3022291

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:29

US3022291

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:29

US3022291

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:32

US3022291

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Sep 2020 19:29:32

US3022291

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:45

US3022291

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:45

US3022291

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:45

US3022291

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:45

US3022291

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:49

US3022291

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Sep 2020 19:29:49

US3022291

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 19:46:45

US3022291

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 19:46:45

US3022291

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Sep 2020 19:46:45

US3022291

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	28 Sep 2020 19:46:45

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '12:46'	(b) (4), (b) (6)	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:46'	System	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.9' C	(b) (4), (b) (6)	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '71'	(b) (4), (b) (6)	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '102'	(b) (4), (b) (6)	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '68'	(b) (4), (b) (6)	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '15:04'	(b) (4), (b) (6)	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '28 Sep 2020 15:04'	System	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.5' C	(b) (4), (b) (6)	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '65'	(b) (4), (b) (6)	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '104'	(b) (4), (b) (6)	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '63'	(b) (4), (b) (6)	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 19:50:17

US3022291

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 19:50:17

US3022291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 19:50:28

US3022291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 19:50:28

US3022291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	(b) (4), (b) (6)	28 Sep 2020 19:50:28

US3022291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	28 Sep 2020 19:50:28

US3022291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 19:50:28

US3022291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 19:50:28

US3022291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 19:50:28

US3022291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 19:50:28

US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Chevon Roberts (b) (4) (b) (4)	28 Sep 2020 18:36:31

US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Chevon Roberts (b) (4) (b) (4)	28 Sep 2020 18:36:31

US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	Chevon Roberts (b) (4) (b) (4)	28 Sep 2020 18:36:31

US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 18:36:31

US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Chevon Roberts (b) (4) (b) (4)	28 Sep 2020 18:36:31

US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '14:34'	Chevon Roberts (b) (4) (b) (4)	28 Sep 2020 18:36:31

US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '28 Sep 2020 14:34'	System	28 Sep 2020 18:36:31

US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Chevon Roberts (b) (4) (b) (4)	28 Sep 2020 18:36:31

US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	28 Sep 2020 18:36:31

US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 18:36:31

US3022291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 19:48:40

US3022291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 19:48:40

US3022291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:02'	(b) (4), (b) (6)	28 Sep 2020 19:48:40

US3022291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '28 Sep 2020 13:02'	System	28 Sep 2020 19:48:40

US3022291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:40:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 19:49:13

US3022291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:40:41

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	28 Sep 2020 19:49:13

US3022291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:40:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 19:49:13

US3022291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:40:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '13:24'	(b) (4), (b) (6)	28 Sep 2020 19:49:13

US3022291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '28 Sep 2020 13:24'	System	28 Sep 2020 19:49:13

US3022291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:40:41

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	28 Sep 2020 19:49:13

US3022291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:40:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 19:49:13

US3022291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:40:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 19:49:13

US3022291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 19:49:13

US3022291

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 19:49:30

US3022291

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Sep 2020 19:49:30

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:02:43', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '72997b46-fa8e-409b-9e5a-0af7fd96d2e5'	System	28 Sep 2020 19:02:56
User entered 'Yes (Y)'	System	28 Sep 2020 19:02:56

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:02:47', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '72997b46-fa8e-409b-9e5a-0af7fd96d2e5' User entered '97.7'	System	28 Sep 2020 19:02:56

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:02:51', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '72997b46-fa8e-409b-9e5a-0af7fd96d2e5'	System	28 Sep 2020 19:02:56
User entered 'No (N)'	System	28 Sep 2020 19:02:56

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:02:54', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '72997b46-fa8e-409b-9e5a-0af7fd96d2e5'	System	28 Sep 2020 19:02:56
User entered '28 Sep 2020 15:02'	System	28 Sep 2020 19:02:56

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 14:54'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 17:24'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:19', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '070660d4-a9d3-4afc-9be8-9db6d8dbcc80'	System	29 Sep 2020 12:18:34
User entered 'Yes (Y)'	System	29 Sep 2020 12:18:34

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:24', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '070660d4-a9d3-4afc-9be8-9db6d8dbcc80'	System	29 Sep 2020 12:18:34
User entered '96.6'	System	29 Sep 2020 12:18:34

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:27', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '070660d4-a9d3-4afc-9be8-9db6d8dbcc80'	System	29 Sep 2020 12:18:34
User entered 'No (N)'	System	29 Sep 2020 12:18:34

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:29', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '070660d4-a9d3-4afc-9be8-9db6d8dbcc80'	System	29 Sep 2020 12:18:34
User entered '29 Sep 2020 08:18'	System	29 Sep 2020 12:18:34

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 18:19'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 2'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:01:40', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'f2aecbc8-381a-4eee-adca-43624fc54da1'	System	30 Sep 2020 04:01:57
User entered 'Yes (Y)'	System	30 Sep 2020 04:01:57

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:01:44', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'f2aecbc8-381a-4eee-adca-43624fc54da1'	System	30 Sep 2020 04:01:57
User entered '97.4'	System	30 Sep 2020 04:01:57

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:01:49', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'f2aecbc8-381a-4eee-adca-43624fc54da1'	System	30 Sep 2020 04:01:57
User entered 'No (N)'	System	30 Sep 2020 04:01:57

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:01:52', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'f2aecbc8-381a-4eee-adca-43624fc54da1' User entered '30 Sep 2020 00:01'	System	30 Sep 2020 04:01:57
	System	30 Sep 2020 04:01:57

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 3'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 4'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-01T23:59:52', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '4cad97df-1696-46f4-9ba9-40fa7cf21a91'	System	02 Oct 2020 16:13:04
User entered 'Yes (Y)'	System	02 Oct 2020 16:13:04

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-01T23:59:56', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '4cad97df-1696-46f4-9ba9-40fa7cf21a91'	System	02 Oct 2020 16:13:04
User entered '97.5'	System	02 Oct 2020 16:13:04

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:01', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '4cad97df-1696-46f4-9ba9-40fa7cf21a91'	System	02 Oct 2020 16:13:04
User entered 'No (N)'	System	02 Oct 2020 16:13:04

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:04', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '4cad97df-1696-46f4-9ba9-40fa7cf21a91'	System	02 Oct 2020 16:13:04
User entered '02 Oct 2020 00:00'	System	02 Oct 2020 16:13:04

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 5'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:13:04', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8137e5c0-10d3-4e39-b0ee-08eb9867f89c'	System	02 Oct 2020 16:13:21
User entered 'Yes (Y)'	System	02 Oct 2020 16:13:21

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:13:08', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8137e5c0-10d3-4e39-b0ee-08eb9867f89c'	System	02 Oct 2020 16:13:21
User entered '96.4'	System	02 Oct 2020 16:13:21

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:13:16', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8137e5c0-10d3-4e39-b0ee-08eb9867f89c'	System	02 Oct 2020 16:13:21
User entered 'No (N)'	System	02 Oct 2020 16:13:21

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:13:18', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8137e5c0-10d3-4e39-b0ee-08eb9867f89c'	System	02 Oct 2020 16:13:21
User entered '02 Oct 2020 12:13'	System	02 Oct 2020 16:13:21

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 6'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:03:19', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'f72e2207-9e3f-4f83-86f1-8d906b50b296'	System	03 Oct 2020 23:03:38
User entered 'Yes (Y)'	System	03 Oct 2020 23:03:38

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:03:25', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'f72e2207-9e3f-4f83-86f1-8d906b50b296'	System	03 Oct 2020 23:03:38
User entered '97.3'	System	03 Oct 2020 23:03:38

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:03:29', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'f72e2207-9e3f-4f83-86f1-8d906b50b296'	System	03 Oct 2020 23:03:38
User entered 'No (N)'	System	03 Oct 2020 23:03:38

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:03:33', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'f72e2207-9e3f-4f83-86f1-8d906b50b296'	System	03 Oct 2020 23:03:38
User entered '03 Oct 2020 19:03'	System	03 Oct 2020 23:03:38

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 7'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:40:41', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '05f17b9d-1661-4f74-929f-023e40576067'	System	05 Oct 2020 14:41:01
User entered 'Yes (Y)'	System	05 Oct 2020 14:41:01

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:40:46', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '05f17b9d-1661-4f74-929f-023e40576067'	System	05 Oct 2020 14:41:01
User entered '97.4'	System	05 Oct 2020 14:41:01

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:40:54', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '05f17b9d-1661-4f74-929f-023e40576067'	System	05 Oct 2020 14:41:01
User entered 'No (N)'	System	05 Oct 2020 14:41:01

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:40:57', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '05f17b9d-1661-4f74-929f-023e40576067'	System	05 Oct 2020 14:41:01
User entered '05 Oct 2020 09:40'	System	05 Oct 2020 14:41:01

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:06', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0f1205b3-8996-467c-9f7b-fcd0459e9e79'	System	28 Sep 2020 19:03:42
User entered 'None (1)'	System	28 Sep 2020 19:03:42

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:28', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0f1205b3-8996-467c-9f7b-fcd0459e9e79'	System	28 Sep 2020 19:03:42
User entered 'No (N)'	System	28 Sep 2020 19:03:42

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:31', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0f1205b3-8996-467c-9f7b-fcd0459e9e79'	System	28 Sep 2020 19:03:42
User entered 'No (N)'	System	28 Sep 2020 19:03:42

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:36', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0f1205b3-8996-467c-9f7b-fcd0459e9e79'	System	28 Sep 2020 19:03:42
User entered 'None (1)'	System	28 Sep 2020 19:03:42

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:40', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0f1205b3-8996-467c-9f7b-fcd0459e9e79'	System	28 Sep 2020 19:03:42
User entered '28 Sep 2020 15:03'	System	28 Sep 2020 19:03:42

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 14:54'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 17:24'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:38', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '528eef98-2c2e-4eea-9a18-6efe985efd2a'	System	29 Sep 2020 12:18:54
User entered 'None (1)'	System	29 Sep 2020 12:18:54

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:41', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '528eef98-2c2e-4eea-9a18-6efe985efd2a'	System	29 Sep 2020 12:18:54
User entered 'No (N)'	System	29 Sep 2020 12:18:54

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:43', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '528eef98-2c2e-4eea-9a18-6efe985efd2a'	System	29 Sep 2020 12:18:54
User entered 'No (N)'	System	29 Sep 2020 12:18:54

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:46', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '528eef98-2c2e-4eea-9a18-6efe985efd2a' User entered 'None (1)'	System	29 Sep 2020 12:18:54
	System	29 Sep 2020 12:18:54

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:51', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '528eef98-2c2e-4eea-9a18-6efe985efd2a'	System	29 Sep 2020 12:18:54
User entered '29 Sep 2020 08:18'	System	29 Sep 2020 12:18:54

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 18:19'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 2'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '61a6e18b-6c43-4d77-9c13-2e90ddcd94'	System	30 Sep 2020 04:02:16
User entered 'None (1)'	System	30 Sep 2020 04:02:16

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:04', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '61a6e18b-6c43-4d77-9c13-2e90ddcd94'	System	30 Sep 2020 04:02:16
User entered 'No (N)'	System	30 Sep 2020 04:02:16

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:07', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '61a6e18b-6c43-4d77-9c13-2e90ddcd94'	System	30 Sep 2020 04:02:16
User entered 'No (N)'	System	30 Sep 2020 04:02:16

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:10', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '61a6e18b-6c43-4d77-9c13-2e90ddcd94'	System	30 Sep 2020 04:02:16
User entered 'None (1)'	System	30 Sep 2020 04:02:16

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:13', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '61a6e18b-6c43-4d77-9c13-2e90ddcd94'	System	30 Sep 2020 04:02:16
User entered '30 Sep 2020 00:02'	System	30 Sep 2020 04:02:16

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 3'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 4'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:08', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fcf777d2-3536-4469-ab1f-94900d4602b5'	System	02 Oct 2020 16:13:05
User entered 'None (1)'	System	02 Oct 2020 16:13:05

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:13', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fcf777d2-3536-4469-ab1f-94900d4602b5' User entered 'No (N)'	System	02 Oct 2020 16:13:05
	System	02 Oct 2020 16:13:05

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:16', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fcf777d2-3536-4469-ab1f-94900d4602b5'	System	02 Oct 2020 16:13:05
User entered 'No (N)'	System	02 Oct 2020 16:13:05

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:22', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fcf777d2-3536-4469-ab1f-94900d4602b5'	System	02 Oct 2020 16:13:05
User entered 'None (1)'	System	02 Oct 2020 16:13:05

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:25', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fcf777d2-3536-4469-ab1f-94900d4602b5' User entered '02 Oct 2020 00:00'	System	02 Oct 2020 16:13:05
	System	02 Oct 2020 16:13:05

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 5'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:13:30', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '142c80c6-c305-44bf-b69e-7a7bcac4d38e'	System	02 Oct 2020 16:13:57
User entered 'None (1)'	System	02 Oct 2020 16:13:57

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:13:38', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '142c80c6-c305-44bf-b69e-7a7bcac4d38e'	System	02 Oct 2020 16:13:57
User entered 'No (N)'	System	02 Oct 2020 16:13:57

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:13:46', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '142c80c6-c305-44bf-b69e-7a7bcac4d38e'	System	02 Oct 2020 16:13:57
User entered 'No (N)'	System	02 Oct 2020 16:13:57

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:13:52', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '142c80c6-c305-44bf-b69e-7a7bcac4d38e' User entered 'None (1)'	System	02 Oct 2020 16:13:57
	System	02 Oct 2020 16:13:57

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:13:55', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '142c80c6-c305-44bf-b69e-7a7bcac4d38e'	System	02 Oct 2020 16:13:57
User entered '02 Oct 2020 12:13'	System	02 Oct 2020 16:13:57

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 6'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:09', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'c21e8dbf-e61e-489b-8ef1-cc16f41ef02e'	System	03 Oct 2020 23:04:44
User entered 'None (1)'	System	03 Oct 2020 23:04:44

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:14', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'c21e8dbf-e61e-489b-8ef1-cc16f41ef02e'	System	03 Oct 2020 23:04:44
User entered 'No (N)'	System	03 Oct 2020 23:04:44

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:17', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'c21e8dbf-e61e-489b-8ef1-cc16f41ef02e'	System	03 Oct 2020 23:04:44
User entered 'No (N)'	System	03 Oct 2020 23:04:44

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:20', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'c21e8dbf-e61e-489b-8ef1-cc16f41ef02e'	System	03 Oct 2020 23:04:44
User entered 'None (1)'	System	03 Oct 2020 23:04:44

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:23', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'c21e8dbf-e61e-489b-8ef1-cc16f41ef02e'	System	03 Oct 2020 23:04:44
User entered '03 Oct 2020 19:04'	System	03 Oct 2020 23:04:44

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 7'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:01', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'dafe8ed1-796f-4193-b311-ea78cc425ef8'	System	05 Oct 2020 14:41:16
User entered 'None (1)'	System	05 Oct 2020 14:41:16

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:05', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'dafe8ed1-796f-4193-b311-ea78cc425ef8'	System	05 Oct 2020 14:41:16
User entered 'No (N)'	System	05 Oct 2020 14:41:16

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:07', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'dafe8ed1-796f-4193-b311-ea78cc425ef8'	System	05 Oct 2020 14:41:16
User entered 'No (N)'	System	05 Oct 2020 14:41:16

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:09', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'dafe8ed1-796f-4193-b311-ea78cc425ef8'	System	05 Oct 2020 14:41:16
User entered 'None (1)'	System	05 Oct 2020 14:41:16

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:11', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'dafe8ed1-796f-4193-b311-ea78cc425ef8' User entered '05 Oct 2020 09:41'	System	05 Oct 2020 14:41:16
	System	05 Oct 2020 14:41:16

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:45', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7a477a84-7082-4acd-be77-0099d0a1c3f6'	System	28 Sep 2020 19:04:06
User entered 'None (0)'	System	28 Sep 2020 19:04:06

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:49', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7a477a84-7082-4acd-be77-0099d0a1c3f6' User entered 'None (0)'	System	28 Sep 2020 19:04:06

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:51', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7a477a84-7082-4acd-be77-0099d0a1c3f6'	System	28 Sep 2020 19:04:06
User entered 'None (0)'	System	28 Sep 2020 19:04:06

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:53', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7a477a84-7082-4acd-be77-0099d0a1c3f6'	System	28 Sep 2020 19:04:06
User entered 'None (0)'	System	28 Sep 2020 19:04:06

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:55', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7a477a84-7082-4acd-be77-0099d0a1c3f6'	System	28 Sep 2020 19:04:06
User entered 'None (0)'	System	28 Sep 2020 19:04:06

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:57', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7a477a84-7082-4acd-be77-0099d0a1c3f6'	System	28 Sep 2020 19:04:06
User entered 'None (0)'	System	28 Sep 2020 19:04:06

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:59', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7a477a84-7082-4acd-be77-0099d0a1c3f6'	System	28 Sep 2020 19:04:06
User entered 'No (N)'	System	28 Sep 2020 19:04:06

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:04:01', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7a477a84-7082-4acd-be77-0099d0a1c3f6'	System	28 Sep 2020 19:04:06
User entered '28 Sep 2020 15:04'	System	28 Sep 2020 19:04:06

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 14:54'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 17:24'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:55', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e4cf4b6f-feae-4dd0-842f-5f3e645fc1a7'	System	29 Sep 2020 12:19:15
User entered 'None (0)'	System	29 Sep 2020 12:19:15

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:56', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e4cf4b6f-feae-4dd0-842f-5f3e645fc1a7'	System	29 Sep 2020 12:19:15
User entered 'None (0)'	System	29 Sep 2020 12:19:15

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:59', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e4cf4b6f-feae-4dd0-842f-5f3e645fc1a7'	System	29 Sep 2020 12:19:15
User entered 'None (0)'	System	29 Sep 2020 12:19:15

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:19:01', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e4cf4b6f-feae-4dd0-842f-5f3e645fc1a7'	System	29 Sep 2020 12:19:15
User entered 'None (0)'	System	29 Sep 2020 12:19:15

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:19:02', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e4cf4b6f-feae-4dd0-842f-5f3e645fc1a7'	System	29 Sep 2020 12:19:15
User entered 'None (0)'	System	29 Sep 2020 12:19:15

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:19:04', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e4cf4b6f-feae-4dd0-842f-5f3e645fc1a7'	System	29 Sep 2020 12:19:15
User entered 'None (0)'	System	29 Sep 2020 12:19:15

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:19:08', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e4cf4b6f-feae-4dd0-842f-5f3e645fc1a7'	System	29 Sep 2020 12:19:15
User entered 'No (N)'	System	29 Sep 2020 12:19:15

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:19:11', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e4cf4b6f-feae-4dd0-842f-5f3e645fc1a7'	System	29 Sep 2020 12:19:15
User entered '29 Sep 2020 08:19'	System	29 Sep 2020 12:19:15

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 18:19'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 2'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:19', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc860e2b-9879-4614-ade9-fac38182efec'	System	30 Sep 2020 04:13:30
User entered 'None (0)'	System	30 Sep 2020 04:13:30

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:22', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc860e2b-9879-4614-ade9-fac38182efec'	System	30 Sep 2020 04:13:30
User entered 'None (0)'	System	30 Sep 2020 04:13:30

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:24', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc860e2b-9879-4614-ade9-fac38182efec'	System	30 Sep 2020 04:13:30
User entered 'None (0)'	System	30 Sep 2020 04:13:30

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:26', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc860e2b-9879-4614-ade9-fac38182efec'	System	30 Sep 2020 04:13:30
User entered 'None (0)'	System	30 Sep 2020 04:13:30

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:29', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc860e2b-9879-4614-ade9-fac38182efec'	System	30 Sep 2020 04:13:30
User entered 'None (0)'	System	30 Sep 2020 04:13:30

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:32', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc860e2b-9879-4614-ade9-fac38182efec'	System	30 Sep 2020 04:13:30
User entered 'None (0)'	System	30 Sep 2020 04:13:30

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:13:24', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc860e2b-9879-4614-ade9-fac38182efec'	System	30 Sep 2020 04:13:30
User entered 'No (N)'	System	30 Sep 2020 04:13:30

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:13:26', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc860e2b-9879-4614-ade9-fac38182efec' User entered '30 Sep 2020 00:13'	System	30 Sep 2020 04:13:30
	System	30 Sep 2020 04:13:30

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 3'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 4'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:33', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ddc73048-66e1-44db-aa5a-527c054d6e55'	System	02 Oct 2020 16:13:05
User entered 'None (0)'	System	02 Oct 2020 16:13:05

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:37', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ddc73048-66e1-44db-aa5a-527c054d6e55'	System	02 Oct 2020 16:13:05
User entered 'None (0)'	System	02 Oct 2020 16:13:05

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:39', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ddc73048-66e1-44db-aa5a-527c054d6e55'	System	02 Oct 2020 16:13:05
User entered 'None (0)'	System	02 Oct 2020 16:13:05

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:41', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ddc73048-66e1-44db-aa5a-527c054d6e55'	System	02 Oct 2020 16:13:05
User entered 'None (0)'	System	02 Oct 2020 16:13:05

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:43', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ddc73048-66e1-44db-aa5a-527c054d6e55'	System	02 Oct 2020 16:13:05
User entered 'None (0)'	System	02 Oct 2020 16:13:05

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:45', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ddc73048-66e1-44db-aa5a-527c054d6e55'	System	02 Oct 2020 16:13:05
User entered 'None (0)'	System	02 Oct 2020 16:13:05

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:48', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ddc73048-66e1-44db-aa5a-527c054d6e55'	System	02 Oct 2020 16:13:05
User entered 'No (N)'	System	02 Oct 2020 16:13:05

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:51', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ddc73048-66e1-44db-aa5a-527c054d6e55'	System	02 Oct 2020 16:13:05
User entered '02 Oct 2020 00:00'	System	02 Oct 2020 16:13:05

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 5'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:14:06', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3bba89a5-3ad3-4436-8268-6f66f7e9afd4'	System	02 Oct 2020 16:15:12
User entered 'None (0)'	System	02 Oct 2020 16:15:12

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:14:09', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3bba89a5-3ad3-4436-8268-6f66f7e9afd4'	System	02 Oct 2020 16:15:12
User entered 'None (0)'	System	02 Oct 2020 16:15:12

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:14:13', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3bba89a5-3ad3-4436-8268-6f66f7e9afd4'	System	02 Oct 2020 16:15:12
User entered 'None (0)'	System	02 Oct 2020 16:15:12

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:14:16', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3bba89a5-3ad3-4436-8268-6f66f7e9afd4'	System	02 Oct 2020 16:15:12
User entered 'None (0)'	System	02 Oct 2020 16:15:12

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:14:31', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3bba89a5-3ad3-4436-8268-6f66f7e9afd4'	System	02 Oct 2020 16:15:12
User entered 'None (0)'	System	02 Oct 2020 16:15:12

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:14:36', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3bba89a5-3ad3-4436-8268-6f66f7e9afd4'	System	02 Oct 2020 16:15:12
User entered 'None (0)'	System	02 Oct 2020 16:15:12

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:15:06', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3bba89a5-3ad3-4436-8268-6f66f7e9afd4'	System	02 Oct 2020 16:15:12
User entered 'No (N)'	System	02 Oct 2020 16:15:12

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:15:10', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3bba89a5-3ad3-4436-8268-6f66f7e9afd4'	System	02 Oct 2020 16:15:12
User entered '02 Oct 2020 12:15'	System	02 Oct 2020 16:15:12

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 6'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:27', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '53e10650-92e6-4835-a614-030c59f21833'	System	03 Oct 2020 23:04:51
User entered 'None (0)'	System	03 Oct 2020 23:04:51

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:29', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '53e10650-92e6-4835-a614-030c59f21833'	System	03 Oct 2020 23:04:51
User entered 'None (0)'	System	03 Oct 2020 23:04:51

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:31', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '53e10650-92e6-4835-a614-030c59f21833'	System	03 Oct 2020 23:04:51
User entered 'None (0)'	System	03 Oct 2020 23:04:51

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:33', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '53e10650-92e6-4835-a614-030c59f21833'	System	03 Oct 2020 23:04:51
User entered 'None (0)'	System	03 Oct 2020 23:04:51

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:38', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '53e10650-92e6-4835-a614-030c59f21833'	System	03 Oct 2020 23:04:51
User entered 'None (0)'	System	03 Oct 2020 23:04:51

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:40', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '53e10650-92e6-4835-a614-030c59f21833'	System	03 Oct 2020 23:04:51
User entered 'None (0)'	System	03 Oct 2020 23:04:51

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:42', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '53e10650-92e6-4835-a614-030c59f21833'	System	03 Oct 2020 23:04:51
User entered 'No (N)'	System	03 Oct 2020 23:04:51

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:44', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '53e10650-92e6-4835-a614-030c59f21833'	System	03 Oct 2020 23:04:51
User entered '03 Oct 2020 19:04'	System	03 Oct 2020 23:04:51

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 18:36:31
User entered 'Day 7'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:14', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'aebdfcb6-6a5f-46e7-8c25-b7514f252aef'	System	05 Oct 2020 14:41:32
User entered 'None (0)'	System	05 Oct 2020 14:41:32

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:16', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'aebdfcb6-6a5f-46e7-8c25-b7514f252aef' User entered 'None (0)'	System	05 Oct 2020 14:41:32

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:17', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'aebdfcb6-6a5f-46e7-8c25-b7514f252aef'	System	05 Oct 2020 14:41:32
User entered 'None (0)'	System	05 Oct 2020 14:41:32

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:19', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'aebdfcb6-6a5f-46e7-8c25-b7514f252aef' User entered 'None (0)'	System	05 Oct 2020 14:41:32

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:20', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'aebdfcb6-6a5f-46e7-8c25-b7514f252aef'	System	05 Oct 2020 14:41:32
User entered 'None (0)'	System	05 Oct 2020 14:41:32

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:22', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'aebdfcb6-6a5f-46e7-8c25-b7514f252aef'	System	05 Oct 2020 14:41:32
User entered 'None (0)'	System	05 Oct 2020 14:41:32

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:25', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'aebdfcb6-6a5f-46e7-8c25-b7514f252aef'	System	05 Oct 2020 14:41:32
User entered 'No (N)'	System	05 Oct 2020 14:41:32

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:29', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'aebdfcb6-6a5f-46e7-8c25-b7514f252aef' User entered '05 Oct 2020 09:41'	System	05 Oct 2020 14:41:32

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 18:36:31

US3022291

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 19:40:31

US3022291

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '05 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 19:40:31

US3022291

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 19:40:31

US3022291

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 19:40:31

US3022291

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 19:40:37

US3022291

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Oct 2020 19:40:37

US3022291

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 18:26:02

US3022291

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 18:26:02

US3022291

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Oct 2020 18:26:02

US3022291

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 18:26:02

US3022291

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 18:50:58

US3022291

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 18:50:58

US3022291

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 14:26:23

US3022291

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '19 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 14:26:23

US3022291

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Oct 2020 14:26:23

US3022291

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 14:26:23

US3022291

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 14:27:10

US3022291

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 14:27:10

US3022291

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 18:35:18

US3022291

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 18:35:18

US3022291

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	23 Oct 2020 18:35:18

US3022291

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	23 Oct 2020 18:35:18

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '08:24'	(b) (4), (b) (6)	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '23 Oct 2020 08:24'	System	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	(b) (4), (b) (6)	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '64'	(b) (4), (b) (6)	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	(b) (4), (b) (6)	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 18:37:37

US3022291

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 18:37:37

US3022291

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 18:38:01

US3022291

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 18:38:01

US3022291

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '08:39'	(b) (4), (b) (6)	23 Oct 2020 18:38:01

US3022291

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '23 Oct 2020 08:39'	System	23 Oct 2020 18:38:01

US3022291

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 18:38:15

US3022291

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Oct 2020 18:38:15

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 64'	System	24 Aug 2020 14:49:01

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-24T00:47:49', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '57e2d337-f23e-434a-902c-54cf5bbfab08'	System	24 Oct 2020 04:47:59
User entered 'No (N)'	System	24 Oct 2020 04:47:59

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-24T00:47:52', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '57e2d337-f23e-434a-902c-54cf5bbfab08'	System	24 Oct 2020 04:47:59
User entered 'No (N)'	System	24 Oct 2020 04:47:59

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-24T00:47:55', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '57e2d337-f23e-434a-902c-54cf5bbfab08' User entered '24 Oct 2020 00:47:55'	System	24 Oct 2020 04:47:59

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 14:49:01

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 71'	System	24 Aug 2020 14:49:01

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-31T00:02:04', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '34f8cbbe-cca1-4dc8-9273-6d2a62cc9383'	System	31 Oct 2020 04:02:19
User entered 'No (N)'	System	31 Oct 2020 04:02:19

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-31T00:02:06', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '34f8cbbe-cca1-4dc8-9273-6d2a62cc9383'	System	31 Oct 2020 04:02:19
User entered 'No (N)'	System	31 Oct 2020 04:02:19

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-31T00:02:11', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '34f8cbbe-cca1-4dc8-9273-6d2a62cc9383' User entered '31 Oct 2020 00:02:11'	System	31 Oct 2020 04:02:19
	System	31 Oct 2020 04:02:19

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 14:49:01

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 78'	System	24 Aug 2020 14:49:01

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-11-07T00:02:15', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '204548c4-9e5f-48bd-af25-daf094a9f98b'	System	07 Nov 2020 05:02:27
User entered 'No (N)'	System	07 Nov 2020 05:02:27

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-11-07T00:02:20', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '204548c4-9e5f-48bd-af25-daf094a9f98b'	System	07 Nov 2020 05:02:27
User entered 'No (N)'	System	07 Nov 2020 05:02:27

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-11-07T00:02:25', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '204548c4-9e5f-48bd-af25-daf094a9f98b'	System	07 Nov 2020 05:02:27
User entered '07 Nov 2020 00:02:25'	System	07 Nov 2020 05:02:27

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 14:49:01

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 14:49:01
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 14:49:01

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '21 Oct 2020 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '25 Oct 2020 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '28 Oct 2020 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '01 Nov 2020 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '04 Nov 2020 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '08 Nov 2020 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '11 Nov 2020 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '15 Nov 2020 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:32:47

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 08:40:41

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 20:40:05
User entered 'No (N)'	Shanice Bennett (b) (4)	16 Sep 2020 19:29:55

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 00:59:48
User entered 'USA-US051-2020-mRNA-1273-P301000013'	System	24 Nov 2020 00:59:42
User entered 'New'	(b) (4), (b) (6)	24 Nov 2020 00:59:42

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:14
Data point term sent to Coder	System	20 Nov 2020 20:43:11
User entered 'Worsening of right knee arthritis'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '09 Nov 2020'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Nov 2020'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 4 (Grade 4)' reason for change:	Shanice Bennett	(b) (4) 20 Nov 2020 20:51:49
Data Entry Error	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Shanice Bennett	(b) (4) 20 Nov 2020 20:42:20
	(b) (4)	

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	20 Nov 2020 20:42:38
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	20 Nov 2020 20:42:20
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	20 Nov 2020 20:42:38
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		20 Nov 2020 20:42:38
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 20:42:38
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	20 Nov 2020 20:42:20
User entered '0'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Nov 2020'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[None](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered 'I'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Pre-planned surgery for worsening for right knee arthritis that started in un/unk/2019'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Nov 2020 20:42:20

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:40:41

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:07

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 09:53:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 09:53:45
Data point term sent to Coder Coding entries removed.	System Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:08:03 17 Sep 2020 21:07:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:36:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:36:47
Data point term sent to Coder User entered 'Diclofenac'	System Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:12 24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:07:34
Query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'IT IS JUST ARTHRITIS IN THE KNEE' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 21:11:01
User opened query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:35:46
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of ARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 14:04:13
Query 'Per DM CLR: Please update the indication to reflect the location/type of ARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'updated' (Site from DM).	Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:07:59
User entered 'right knee ARTHRITIS' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:07:55
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of ARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Sep 2020 03:27:54
User entered 'Arthritis'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '75-200'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit or the dosage. Reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 13:30:02
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit or the dosage. Reconcile and update as appropriate.' answered with 'updated' (Site from DM).	Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:08:40
User entered 'mg (mg)' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:08:36
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit or the dosage. Reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Sep 2020 03:27:35
User entered 'tablet (TABLET)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

[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: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 21:35:46
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 21:35:46
Data point term sent to Coder	System	17 Sep 2020 21:08:05
Coding entries removed.	Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:08:04
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:37:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:37:31
Data point term sent to Coder	System	24 Aug 2020 19:36:13
User entered 'Celecoxib'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:07:49
Query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate' answered with 'IT IS JUST ARTHRITIS IN THE KNEE' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 21:11:24
User opened query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:36:15
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of ARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate. (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 14:04:28
Query 'Per DM CLR: Please update the indication to reflect the location/type of ARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate. answered with 'updated' (Site from DM).	Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:08:08
User entered 'right knee ARTHRITIS' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:08:04
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of ARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate. (Site from DM).	(b) (4), (b) (6)	12 Sep 2020 03:28:28
User entered 'Arthritis'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: OLMESARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:38:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:38:40
Data point term sent to Coder	System	24 Aug 2020 19:37:17
User entered 'Olmesartan'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose. Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 21:44:24
User entered '10' reason for change: Data Entry Error	Shanice Bennett (b) (4)	22 Sep 2020 18:49:58
Query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose. Reconcile and update as appropriate. ' answered with 'this dosage is correct ' (Site from DM).	Shanice Bennett (b) (4)	22 Sep 2020 18:49:20
User opened query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose. Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Sep 2020 03:30:50
User entered '12.5'	Stella Yoon (b) (4)	24 Aug 2020 19:36:34

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'un Jan 2020'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:36:34

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:36:34

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 19:36:34

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM-Coding: Please update the term to include the active ingredient name(s) in brackets next to the drug to enable coding. ' (Site from System).	Coder Import (b) (4)	24 Nov 2020 08:25:05
Data point term sent to Coder	System	20 Nov 2020 20:44:12
User entered 'ALQUIST'	Shanice Bennett (b) (4)	20 Nov 2020 20:43:47
	(b) (4)	

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

[Indication](#)

Audit	User	Time (GMT)
User entered 'WORSENING RIGHT KNEE ARTHRITIS'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2.5'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '09 Nov 2020'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:40:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:01
Data point term sent to Coder	System	20 Nov 2020 20:46:16
User entered 'OXYCODONE/ACETAMINOPHEN'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

[Indication](#)

Audit	User	Time (GMT)
User entered 'WORSENING RIGHT KNEE ARTHRITIS'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10/325'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Nov 2020'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:40:41

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 20:45:24
User entered 'No (N)'	Shanice Bennett (b) (4)	16 Sep 2020 19:30:00

US3022291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:40:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Nov 2020'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:44

US3022291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:40:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'RIGHT KNEE REPLACEMENT'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:44

US3022291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:40:41

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:44

US3022291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:40:41

If indication is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:44

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'USA-US051-2020-MRNA-1273-P301000013'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Yes (Y)'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Yes (Y)'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Paul'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Bradley'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered '340 Eisenhower Dr.'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Savannah'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'GA'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered '31406'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	24 Nov 2020 01:00:12

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Nov 2020 01:00:12

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'USA-US051-2020-MRNA-1273-P301000013'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Yes (Y)'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Yes (Y)'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Paul'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Bradley'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered '340 Eisenhower Dr.'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Savannah'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'GA'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered '31406'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	24 Nov 2020 01:00:12

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Nov 2020 01:00:12

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:40:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 01:00'	System	24 Nov 2020 01:00:12

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:40:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 01:00:12