

US3012263 (Prod: Benchmark Research)

Generated By: (b) (6)

Generated On: 26 Nov 2020 08:43:26

All time stamps listed in this document are displayed in GMT

US3012263

Form: Participant Creation

Generated On: 26 Nov 2020 08:43:26

[Participant ID](#)

US3012263

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

US3012263

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3012263

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:26

Date of Birth (MMM yyyy)	(b) (6) 1969
Age	50
Age Units	YEARS
Age (Derived)	50
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3012263

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:26

Date of Informed Consent (<i>dd MMM yyyy</i>)	02 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3012263

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 08:43:26

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

Yes ☒

No ☐

US3012263

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 08:43:26

Were any significant conditions reported?

Yes ☒

No ☐

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:26

Condition	GENERAL MYALGIAS, SECONDARY TO WORK
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)	

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:26

Condition	DIABETIC NEUROPATHY, LEFT FOOT SENSORY
Start date (dd MMM yyyy)	UN FEB 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)	FEB 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	02 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:45 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 15:45
Height (<i>xxx.x</i>)	66.0 in
Weight (<i>xxx.x</i>)	184.2 lb
BMI (<i>xxx.x</i>)	29.79282 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)	

US3012263

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 2020

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

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

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 True

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

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3012263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:26

What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 145734

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 ☒

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:26

Height	ND - Not Done
Weight	ND - Not Done

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

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)	02 SEP 2020
Time of assessment (00:00-23:59)	15:45 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 15:45
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

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)	02 SEP 2020
Time of assessment (00:00-23:59)	18:04 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 18:04
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3012263

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:26

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3012263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

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)	02 SEP 2020
What was the treatment time? (00:00-23:59)	17:21 (24 HR)
Treatment Date and Time (derived)	02 SEP 2020 17:21
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

US3012263

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	02 SEP 2020
Collection time (<i>00:00-23:59</i>)	16:43 (24 HR)
Collection date and time (derived)	02 SEP 2020 16:43

US3012263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:43:26

Collection date (<i>dd MMM yyyy</i>)			02 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:29	02 SEP 2020 16:29
Nasopharyngeal Swab 2	No		

US3012263

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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 SEP 2020 18:00

PC Open Date & Time

02 SEP 2020 17:41

PC Close Date & Time

02 SEP 2020 20:11

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

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 96.3 °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	02 SEP 2020 22:28
PC Open Date & Time	02 SEP 2020 21:06
PC Close Date & Time	03 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °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

03 SEP 2020 23:04

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °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

05 SEP 2020 08:38

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:26

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

96.3 °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

05 SEP 2020 23:23

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:26

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 00:04

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:26

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

100.3 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

07 SEP 2020 21:36

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 21:00

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

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

02 SEP 2020 18:01

PC Open Date & Time

02 SEP 2020 17:41

PC Close Date & Time

02 SEP 2020 20:11

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

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

02 SEP 2020 22:29

PC Open Date & Time

02 SEP 2020 21:06

PC Close Date & Time

03 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:26

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

03 SEP 2020 23:05

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:26

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

05 SEP 2020 08:38

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:26

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

05 SEP 2020 23:24

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:26

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

07 SEP 2020 00:04

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:26

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

07 SEP 2020 21:37

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:26

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

08 SEP 2020 21:00

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 18:02
PC Open Date & Time	02 SEP 2020 17:41
PC Close Date & Time	02 SEP 2020 20:11

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 22:29
PC Open Date & Time	02 SEP 2020 21:06
PC Close Date & Time	03 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

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 ☒

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 23:05
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

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 ☒

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 08:39
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

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 ☒

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 23:24
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:26

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 ☒

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:26

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 00:05
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

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 ☒

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 21:39
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

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 ☒

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 21:01
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3012263

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

Was Contact Attempted?

Yes ☒

No ☐

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

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012263

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012263

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

Was Contact Attempted?

Yes ☒

No ☐

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

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012263

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012263

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

Was Contact Attempted?

Yes ☒

No ☐

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

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012263

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012263

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

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)	30 SEP 2020
Time of assessment (00:00-23:59)	14:04 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 14:04
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

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)	30 SEP 2020
Time of assessment (00:00-23:59)	17:54 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 17:54
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 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)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3012263

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3012263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

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)	30 SEP 2020
What was the treatment time? (00:00-23:59)	17:15 (24 HR)
Treatment Date and Time (derived)	30 SEP 2020 17:15
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

US3012263

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	30 SEP 2020
Collection time (<i>00:00-23:59</i>)	16:30 (24 HR)
Collection date and time (derived)	30 SEP 2020 16:30

US3012263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:43:26

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:20	30 SEP 2020 16:20
Nasopharyngeal Swab 2	No		

US3012263

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 17:49

PC Open Date & Time

30 SEP 2020 17:35

PC Close Date & Time

30 SEP 2020 20:05

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

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 95.3 °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 SEP 2020 22:18

PC Open Date & Time 30 SEP 2020 21:00

PC Close Date & Time 01 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °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 01:11

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °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

02 OCT 2020 22:49

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:26

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

96.0 °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

04 OCT 2020 00:01

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:26

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**

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 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:26

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

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

06 OCT 2020 00:52

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:26

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

95.5 °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

06 OCT 2020 21:52

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

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

30 SEP 2020 17:50

PC Open Date & Time

30 SEP 2020 17:35

PC Close Date & Time

30 SEP 2020 20:05

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

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

30 SEP 2020 22:19

PC Open Date & Time

30 SEP 2020 21:00

PC Close Date & Time

01 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:26

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

02 OCT 2020 01:12

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:26

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

02 OCT 2020 22:49

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:26

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

04 OCT 2020 00:02

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:26

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 ☐

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

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:26

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

06 OCT 2020 00:52

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:26

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

06 OCT 2020 21:53

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 17:50
PC Open Date & Time	30 SEP 2020 17:35
PC Close Date & Time	30 SEP 2020 20:05

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 22:19
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PC Open Date & Time	30 SEP 2020 21:00
---------------------	-------------------

PC Close Date & Time	01 OCT 2020 11:59
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US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

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 ☒

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

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 ☒

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 22:50
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

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 ☒

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 00:02
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

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 ☒

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 00:52
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

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 ☒

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 21:53
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3012263

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

Was Contact Attempted?

Yes ☒

No ☐

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

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012263

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012263

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

Was Contact Attempted?

Yes ☒

No ☐

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

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012263

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012263

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

Was Contact Attempted?

Yes ☒

No ☐

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

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012263

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012263

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	15:55 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 15:55
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	97 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012263

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:26

Was the physical examination performed?

Yes ☐
No ☒

Date of examination (dd MMM yyyy)

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

US3012263

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	30 OCT 2020
Collection time (<i>00:00-23:59</i>)	16:07 (24 HR)
Collection date and time (derived)	30 OCT 2020 16:07

US3012263

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	17 NOV 2020 13:01:30
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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="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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2020 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01
Patient Cloud Close Date & Time	10 NOV 2020 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01
Patient Cloud Close Date & Time	17 NOV 2020 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 10:30:24

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 138

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

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

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

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

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

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

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

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 145

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

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

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

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

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

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

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

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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23 FEB 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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

Date and time of submission

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26 FEB 2021 00:01

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02 MAR 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 194

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

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

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

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

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

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

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

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2021 00:01

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16 MAR 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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="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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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23 MAR 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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30 MAR 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 215

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

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

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

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

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

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

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

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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06 APR 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 222

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

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

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

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

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

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

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

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2021 00:01

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13 APR 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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23 APR 2021 00:01

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27 APR 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	29 JUN 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	06 JUL 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	31 AUG 2021 23:59
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US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	18 JAN 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01
Patient Cloud Close Date & Time	29 MAR 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	19 APR 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01
Patient Cloud Close Date & Time	07 JUN 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

DAY 719

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

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

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

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

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

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

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

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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="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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	13 SEP 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	27 SEP 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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="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"/>

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3012263

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3012263

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 08:43:26

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"/>

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Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 08:43:26

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3012263

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 08:43:26

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

AEID	
Adverse event	LOOSE MOLAR
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

332 of 2026

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

AEID	USA-US006-2020-MRNA-1273-P30 1000003
Adverse event	GUNSHOT WOUND, RIGHT SHOULDER AND SPINE
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)	08 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	09 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	15 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)

334 of 2026

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

SUBJECT REPORTED BEING
SHOT DURING AN
INVASION/BREAK IN AT HIS
HOME. SUBJECT WAS SHOT
TWICE, ONCE IN THE RIGHT
SHOULDER AND THE SECOND
PIERCED BOTH LUNGS
CAUSING COLLAPSE AND IS
CURRENTLY LODGED IN
SUBJECT'S SPINE. CURRENTLY
HOSPITALIZED.

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

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

AEID	USA-US006-2020-MRNA-1273-P30 1000003
Adverse event	BILATERAL LUNG COLLAPSE
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)	15 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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	15 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)

337 of 2026

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

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	False
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	

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

SUBJECT REPORTED BEING
SHOT DURING AN
INVASION/BREAK IN AT HIS
HOME. SUBJECT WAS SHOT
TWICE, ONCE IN THE RIGHT
SHOULDER AND THE SECOND
PIERCED BOTH LUNGS
CAUSING COLLAPSE AND IS
CURRENTLY LODGED IN
SUBJECT'S SPINE. CURRENTLY
HOSPITALIZED.

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

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

AEID	
Adverse event	POST-TRAUMATIC ANXIETY
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 checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

340 of 2026

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

AEID	
Adverse event	RASH, BACK AND BUTTOCKS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

342 of 2026

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

AEID

Adverse event

COMPOUND FRACTURE, T4
AND T3 RIBS, SECONDARY TO
GUNSHOT WOUND

Was this a medically-attended AE?

Yes ☒
No ☐

Was this a Solicited Adverse Reaction?

Yes ☐
No ☒

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

Yes ☐
No ☒

Start date (dd MMM yyyy)

09 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒
No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒
Grade 2/Moderate ☐
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death ☐ False

Life threatening ☐ False

Requires inpatient or prolongation of existing Hospitalization ☐ False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

v6.020 DTW (1102)

344 of 2026

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:43:26

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

Yes ☒

No ☐

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

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

Name of Medication	GLYBURIDE/METFORMIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETES, TYPE II
Dose per administration	5/500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

	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 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

	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 2008
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"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

Name of Medication	IBUPROFEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	GENERAL MYALGIAS
Dose per administration	400
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

	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 2005	
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"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

Name of Medication	GABAPENTIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETIC NEUROPATHY L FOOT SENSORY
Dose per administration	600
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"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

Name of Medication	IBUPROFEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETIC NEUROPATHY L FOOT SENSORY
Dose per administration	400
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		UN FEB 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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CHILLS
Dose per administration	1000
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

	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)		07 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		07 SEP 2020
<hr/>		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
Interval Dosage Definition (derived)		802 <input type="checkbox"/>
		803 <input type="checkbox"/>
		804 <input type="checkbox"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

Name of Medication	AMOXICILIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	MOLAR EXTRACTION
Dose per administration	875
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

	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)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

Name of Medication	NORCO
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	MOLAR EXTRACTION
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"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

Name of Medication	ROBAXIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	PAIN, DUE TO GUNSHOT WOUND (AE #2)
Dose per administration	500
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input checked="" type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		15 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	PAIN, DUE TO GUNSHOT WOUND (AE #2)
Dose per administration	1000
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

	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"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

Name of Medication	TRAMADOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	PAIN, DUE TO GUNSHOT WOUND (AE #2)
Dose per administration	50
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

	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)		15 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"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

Name of Medication	ALPRAZOLAM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANXIETY (AE #4)
Dose per administration	2
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

	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)		18 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"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

Name of Medication	METHOCARBAMOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	PAIN, DUE TO GUNSHOT WOUND (AE #2)
Dose per administration	500
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

	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)		18 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"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

Name of Medication	CLOTRIMAZOLE 1%
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	RASH (AE #5)
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	APPLICATION
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 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"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

Name of Medication	GLIPIZIDE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETES, TYPE II (WHILE HOSPITALIZED)
Dose per administration	5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input 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"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 15 NOV 2020		
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"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

Name of Medication	INSULIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETES, TYPE II (WHILE HOSPITALIZED)
Dose per administration	NA
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	SLIDING SCALE
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		15 NOV 2020
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"/>

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:43:26

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 08:43:26

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
16 SEP 2020	MOLAR EXTRACTION	Adverse Event	
09 NOV 2020	BILATERAL CHEST TUBE PLACEMENT	Adverse Event	
09 NOV 2020	CT SCAN - CHEST	Adverse Event	
09 NOV 2020	CT SCAN - ABDOMEN AND PELVIS	Adverse Event	
11 NOV 2020	CHEST XRAY	Adverse Event	
12 NOV 2020	CHEST XRAY	Adverse Event	

US3012263

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:43:26

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

US3012263

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 08:43:26

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 ☐

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

SAEID	USA-US006-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:43:26

SAEID	USA-US006-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	12/NOV/2020 11:30
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

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:43:26

SAEID	USA-US006-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	23/NOV/2020 20:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3012263 (Prod: Benchmark Research)

US3012263

Form: Participant Creation

Generated On: 26 Nov 2020 08:43:26

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3012263'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Sep 2020 20:39:42

US3012263

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:00

US3012263

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Sep 2020 20:39:43

US3012263

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:00

US3012263

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	02 Sep 2020 22:08:00

US3012263

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered (b) (6) 1969'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Sep 2020 20:39:44

US3012263

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:26

[Age](#)

Audit	User	Time (GMT)
User entered '50'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:26

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	02 Sep 2020 22:08:11

US3012263

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:26

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '50'	System	02 Sep 2020 22:08:20

US3012263

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:26

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:26

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:26

[White](#)

Audit	User	Time (GMT)
User entered 'I'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:26

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:26

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:26

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:26

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:26

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:26

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:26

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:26

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:11

US3012263

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:26

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:20

US3012263

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	02 Sep 2020 22:08:20

US3012263

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '2020'	System	02 Sep 2020 22:08:20

US3012263

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:26

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:20

US3012263

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:20

US3012263

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:20

US3012263

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:26

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:20

US3012263

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:26

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:20

US3012263

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:26

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Sep 2020 20:39:43

US3012263

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:26

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Sep 2020 22:08:23

US3012263

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:23

US3012263

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 08:43:26

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:08:43

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:26

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental and periodontal infections and inflammations, PT: Dental caries, LLT: Dental caries - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:08:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:08:56
Data point term sent to Coder	System	02 Sep 2020 22:10:15
User entered 'dental caries, left molar'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:35

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:35

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:35

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:35

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:35

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:35

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	02 Sep 2020 22:09:35

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '2018'	System	02 Sep 2020 22:09:35

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:09:35

US3012263

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:09:35

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 22:10:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 22:10:58
Data point term sent to Coder	System	02 Sep 2020 22:10:15
User entered 'diabetes, type ii'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '2008'	System	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:09:47

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 22:10:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 22:10:57
Data point term sent to Coder	System	02 Sep 2020 22:10:16
User entered 'hypertension'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '2008'	System	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:10:03

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:21:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:21:58
Data point term sent to Coder	System	02 Sep 2020 22:11:20
User entered 'general myalgias, secondary to work'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:36

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:36

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:36

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:36

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:36

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:10:36

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	02 Sep 2020 22:10:36

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '2005'	System	02 Sep 2020 22:10:36

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:10:36

US3012263

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:10:36

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:26

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 09:51:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 09:51:33
Data point term sent to Coder	System	29 Oct 2020 20:25:03
Coding entries removed.	Pamela Fidler (b) (4) (b) (4) (b) (4)	29 Oct 2020 20:24:39
User entered 'DIABETIC NEUROPATHY, LEFT FOOT Sensory' reason for change: Data Entry Error	Pamela Fidler (b) (4) (b) (4)	29 Oct 2020 20:24:39
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 05:54:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 05:54:39
Data point term sent to Coder	System	02 Sep 2020 22:22:37
User entered 'diabetic neuropathy, left foot'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:22:11

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'UN Feb 2019'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:22:11

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:22:11

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:22:11

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:22:11

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:22:11

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Feb 2019'	System	02 Sep 2020 22:22:11

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '2019'	System	02 Sep 2020 22:22:11

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:22:11

US3012263

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:22:11

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:30

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:30

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '15:45'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:30

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '02 Sep 2020 15:45'	System	02 Sep 2020 22:25:30

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '66.0' in	Jennifer Leyva (b) (4)	02 Sep 2020 22:25:30
DataPoint set to visible.	(b) (4) System	02 Sep 2020 22:08:23

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '184.2' lb	Jennifer Leyva (b) (4)	02 Sep 2020 22:25:30
DataPoint set to visible.	(b) (4) System	02 Sep 2020 22:08:23

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '29.79282'	System	02 Sep 2020 22:25:30
DataPoint set to visible.	System	02 Sep 2020 22:08:23

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	02 Sep 2020 22:25:30
DataPoint set to visible.	System	02 Sep 2020 22:08:23

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: per CCG,"ND" should be recorded for TEMPERATURE,PULSE,RESPIRATORY RATE,SYSTOLIC BP, and DIASTOLIC Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 07:30:10
Query 'Per CDM: per CCG,"ND" should be recorded for TEMPERATURE,PULSE,RESPIRATORY RATE,SYSTOLIC BP, and DIASTOLIC Please update accordingly.' answered with 'Updated' (Site from DM).	Pamela Fidler (b) (4)	13 Oct 2020 15:31:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Pamela Fidler (b) (4)	13 Oct 2020 15:31:03
User opened query 'Per CDM: per CCG,"ND" should be recorded for TEMPERATURE,PULSE,RESPIRATORY RATE,SYSTOLIC BP, and DIASTOLIC Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 12:17:23
User entered '98.5' F	Jennifer Leyva (b) (4)	02 Sep 2020 22:25:30

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Pamela Fidler (b) (4) [REDACTED]	13 Oct 2020 15:31:03
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:30

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:30

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Pamela Fidler (b) (4)	13 Oct 2020 15:31:03
User entered '90'	Jennifer Leyva (b) (4)	02 Sep 2020 22:25:30
	(b) (4)	

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Sep 2020 22:25:30

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Pamela Fidler (b) (4)	13 Oct 2020 15:31:03
User entered '18'	Jennifer Leyva (b) (4)	02 Sep 2020 22:25:30
	(b) (4)	

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Sep 2020 22:25:30

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Pamela Fidler (b) (4) [REDACTED] [REDACTED]	13 Oct 2020 15:31:03
User entered '136'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:30

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 22:25:30

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Pamela Fidler (b) (4) [REDACTED] [REDACTED]	13 Oct 2020 15:31:03
User entered '84'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:30

US3012263

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 22:25:30

US3012263

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:36

US3012263

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '02 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:25:36

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

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)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

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)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

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)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

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)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

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)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

Other

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

No Risk Identified

Audit	User	Time (GMT)
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

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'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

Other

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:26

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:24

US3012263

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:45

US3012263

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '02 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:45

US3012263

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:26:45

US3012263

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	02 Sep 2020 22:26:45

US3012263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	02 Sep 2020 21:54:35

US3012263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:26

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '145734'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	02 Sep 2020 21:54:35

US3012263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:26

[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]	02 Sep 2020 21:54:35

US3012263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:27:19

US3012263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:27:19

US3012263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:27:19

US3012263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:26

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:27:19

US3012263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:26

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:27:19

US3012263

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:26

[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)	02 Nov 2020 13:06:04
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'update' (Site from DM).	Pamela Fidler (b) (4)	28 Oct 2020 15:37:36
User entered 'No (N)'	Pamela Fidler (b) (4)	28 Oct 2020 15:37:33
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:35:16
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:01:48
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:01:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:26

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:26

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:26

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:26

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '15:45'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '02 Sep 2020 15:45'	System	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.5' F	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '90'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '18'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '136'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '84'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:26

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:26

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:17

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '18:04'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '02 Sep 2020 18:04'	System	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '80'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '16'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '136'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '87'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 23:06:47

US3012263

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:26

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:25

US3012263

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:25

US3012263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:57:31

US3012263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:57:31

US3012263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:57:31

US3012263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 22:57:31

US3012263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '02 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:57:31

US3012263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '17:21'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:57:31

US3012263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '02 Sep 2020 17:21'	System	02 Sep 2020 22:57:31

US3012263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:57:31

US3012263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	02 Sep 2020 22:57:31

US3012263

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 22:57:31

US3012263

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:47

US3012263

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:47

US3012263

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:43'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:47

US3012263

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '02 Sep 2020 16:43'	System	02 Sep 2020 22:30:47

US3012263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:43:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:58

US3012263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:26

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:58

US3012263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:58

US3012263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '16:29'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:58

US3012263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '02 Sep 2020 16:29'	System	02 Sep 2020 22:30:58

US3012263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:26

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jennifer Leyva (b) (4)	02 Sep 2020 22:30:58

US3012263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:58

US3012263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:30:58

US3012263

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:30:58

US3012263

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:31:01

US3012263

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 22:31:01

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T17:59:50', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '65b8bdcc-6481-454e-b838-d65936b44265'	System	02 Sep 2020 23:00:16
User entered 'Yes (Y)'	System	02 Sep 2020 23:00:16

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T17:59:57', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '65b8bdcc-6481-454e-b838-d65936b44265'	System	02 Sep 2020 23:00:16
User entered '98.4'	System	02 Sep 2020 23:00:16

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:00:04', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '65b8bdcc-6481-454e-b838-d65936b44265'	System	02 Sep 2020 23:00:16
User entered 'No (N)'	System	02 Sep 2020 23:00:16

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:00:12', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '65b8bdcc-6481-454e-b838-d65936b44265'	System	02 Sep 2020 23:00:16
User entered '02 Sep 2020 18:00'	System	02 Sep 2020 23:00:16

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 17:41'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 20:11'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:27:15', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ab5bf005-fa33-4e1e-be08-3979477ead79'	System	03 Sep 2020 03:28:27
User entered 'Yes (Y)'	System	03 Sep 2020 03:28:27

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:28:12', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ab5bf005-fa33-4e1e-be08-3979477ead79'	System	03 Sep 2020 03:28:27
User entered '96.3'	System	03 Sep 2020 03:28:27

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:28:17', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ab5bf005-fa33-4e1e-be08-3979477ead79'	System	03 Sep 2020 03:28:27
User entered 'No (N)'	System	03 Sep 2020 03:28:27

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:28:22', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ab5bf005-fa33-4e1e-be08-3979477ead79'	System	03 Sep 2020 03:28:27
User entered '02 Sep 2020 22:28'	System	03 Sep 2020 03:28:27

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 21:06'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 2'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:04:07', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f556ba7a-ac2f-406b-b695-618be924685f'	System	04 Sep 2020 04:04:33
User entered 'Yes (Y)'	System	04 Sep 2020 04:04:33

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:04:21', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f556ba7a-ac2f-406b-b695-618be924685f'	System	04 Sep 2020 04:04:33
User entered '96.0'	System	04 Sep 2020 04:04:33

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:04:26', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f556ba7a-ac2f-406b-b695-618be924685f'	System	04 Sep 2020 04:04:33
User entered 'No (N)'	System	04 Sep 2020 04:04:33

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:04:31', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f556ba7a-ac2f-406b-b695-618be924685f'	System	04 Sep 2020 04:04:33
User entered '03 Sep 2020 23:04'	System	04 Sep 2020 04:04:33

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 3'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:38:06', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '20f868c8-952a-47aa-bf95-f7976ae0073e'	System	05 Sep 2020 13:38:22
User entered 'Yes (Y)'	System	05 Sep 2020 13:38:22

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:38:11', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '20f868c8-952a-47aa-bf95-f7976ae0073e'	System	05 Sep 2020 13:38:22
User entered '96.0'	System	05 Sep 2020 13:38:22

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:38:15', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '20f868c8-952a-47aa-bf95-f7976ae0073e'	System	05 Sep 2020 13:38:22
User entered 'No (N)'	System	05 Sep 2020 13:38:22

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:38:19', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '20f868c8-952a-47aa-bf95-f7976ae0073e'	System	05 Sep 2020 13:38:22
User entered '05 Sep 2020 08:38'	System	05 Sep 2020 13:38:22

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 4'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:23:36', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '8dabdf28-d617-4a9b-99fe-ccda12a48a66'	System	06 Sep 2020 04:23:55
User entered 'Yes (Y)'	System	06 Sep 2020 04:23:55

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:23:42', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '8dabdf28-d617-4a9b-99fe-ccda12a48a66'	System	06 Sep 2020 04:23:55
User entered '96.3'	System	06 Sep 2020 04:23:55

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:23:48', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '8dabdf28-d617-4a9b-99fe-ccda12a48a66'	System	06 Sep 2020 04:23:55
User entered 'No (N)'	System	06 Sep 2020 04:23:55

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:23:51', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '8dabdf28-d617-4a9b-99fe-ccda12a48a66'	System	06 Sep 2020 04:23:55
User entered '05 Sep 2020 23:23'	System	06 Sep 2020 04:23:55

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 5'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:07', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '52861067-ad13-4285-87cb-8fac601e8ba8'	System	07 Sep 2020 05:04:26
User entered 'Yes (Y)'	System	07 Sep 2020 05:04:26

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:13', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '52861067-ad13-4285-87cb-8fac601e8ba8'	System	07 Sep 2020 05:04:26
User entered '96.8'	System	07 Sep 2020 05:04:26

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:18', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '52861067-ad13-4285-87cb-8fac601e8ba8'	System	07 Sep 2020 05:04:26
User entered 'No (N)'	System	07 Sep 2020 05:04:26

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:22', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '52861067-ad13-4285-87cb-8fac601e8ba8'	System	07 Sep 2020 05:04:26
User entered '07 Sep 2020 00:04'	System	07 Sep 2020 05:04:26

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 6'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:35:48', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'e28e037d-4964-4198-8ec6-d76320d5a48f'	System	08 Sep 2020 02:36:56
User entered 'Yes (Y)'	System	08 Sep 2020 02:36:56

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:36:08', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'e28e037d-4964-4198-8ec6-d76320d5a48f'	System	08 Sep 2020 02:36:56
User entered '100.3'	System	08 Sep 2020 02:36:56

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:26

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:36:18', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'e28e037d-4964-4198-8ec6-d76320d5a48f'	System	08 Sep 2020 02:36:56
User entered 'Yes (Y)'	System	08 Sep 2020 02:36:56

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 09:50:27
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'MEDICATION HAS BEEN ADDED' (Site from System).	Lamar Box (b) (4)	18 Sep 2020 19:05:35
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	08 Sep 2020 02:36:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:36:35', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'e28e037d-4964-4198-8ec6-d76320d5a48f'	System	08 Sep 2020 02:36:56
User entered '1'	System	08 Sep 2020 02:36:56

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:36:35', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'e28e037d-4964-4198-8ec6-d76320d5a48f' User entered '0'	System	08 Sep 2020 02:36:56

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:36:53', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'e28e037d-4964-4198-8ec6-d76320d5a48f'	System	08 Sep 2020 02:36:56
User entered '07 Sep 2020 21:36'	System	08 Sep 2020 02:36:56

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 7'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T20:59:51', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '9b56be2b-606a-41a0-9707-f7505bb60e5c'	System	09 Sep 2020 02:00:17
User entered 'Yes (Y)'	System	09 Sep 2020 02:00:17

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:00:06', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '9b56be2b-606a-41a0-9707-f7505bb60e5c'	System	09 Sep 2020 02:00:17
User entered '98.1'	System	09 Sep 2020 02:00:17

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:00:10', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '9b56be2b-606a-41a0-9707-f7505bb60e5c'	System	09 Sep 2020 02:00:17
User entered 'No (N)'	System	09 Sep 2020 02:00:17

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:00:14', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '9b56be2b-606a-41a0-9707-f7505bb60e5c'	System	09 Sep 2020 02:00:17
User entered '08 Sep 2020 21:00'	System	09 Sep 2020 02:00:17

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-09-02T18:00:35', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '8ddb3383-4ff6-4bd3-9892-544d12850254'	System	02 Sep 2020 23:01:11
User entered 'None (1)'	System	02 Sep 2020 23:01:11

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:00:43', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '8ddb3383-4ff6-4bd3-9892-544d12850254'	System	02 Sep 2020 23:01:11
User entered 'No (N)'	System	02 Sep 2020 23:01:11

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:00:50', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '8ddb3383-4ff6-4bd3-9892-544d12850254'	System	02 Sep 2020 23:01:11
User entered 'No (N)'	System	02 Sep 2020 23:01:11

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-09-02T18:00:59', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '8ddb3383-4ff6-4bd3-9892-544d12850254'	System	02 Sep 2020 23:01:11
User entered 'None (1)'	System	02 Sep 2020 23:01:11

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:01:05', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '8ddb3383-4ff6-4bd3-9892-544d12850254'	System	02 Sep 2020 23:01:11
User entered '02 Sep 2020 18:01'	System	02 Sep 2020 23:01:11

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 17:41'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 20:11'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-09-02T22:28:36', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dad857da-12e7-4c9d-bc7f-e58fa88635ad'	System	03 Sep 2020 03:29:06
User entered 'None (1)'	System	03 Sep 2020 03:29:06

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:28:44', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dad857da-12e7-4c9d-bc7f-e58fa88635ad'	System	03 Sep 2020 03:29:06
User entered 'No (N)'	System	03 Sep 2020 03:29:06

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:28:49', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dad857da-12e7-4c9d-bc7f-e58fa88635ad'	System	03 Sep 2020 03:29:06
User entered 'No (N)'	System	03 Sep 2020 03:29:06

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

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 (925f6005fee9c9e7)', Time: '2020-09-02T22:28:56', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dad857da-12e7-4c9d-bc7f-e58fa88635ad'	System	03 Sep 2020 03:29:06
User entered 'None (1)'	System	03 Sep 2020 03:29:06

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:29:03', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dad857da-12e7-4c9d-bc7f-e58fa88635ad'	System	03 Sep 2020 03:29:06
User entered '02 Sep 2020 22:29'	System	03 Sep 2020 03:29:06

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 21:06'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 2'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-09-03T23:04:44', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '02af94a6-16c2-4fc4-aae4-27e3b9b696c2'	System	04 Sep 2020 04:05:10
User entered 'None (1)'	System	04 Sep 2020 04:05:10

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:04:47', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '02af94a6-16c2-4fc4-aae4-27e3b9b696c2'	System	04 Sep 2020 04:05:10
User entered 'No (N)'	System	04 Sep 2020 04:05:10

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:04:52', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '02af94a6-16c2-4fc4-aae4-27e3b9b696c2'	System	04 Sep 2020 04:05:10
User entered 'No (N)'	System	04 Sep 2020 04:05:10

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-09-03T23:04:59', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '02af94a6-16c2-4fc4-aae4-27e3b9b696c2'	System	04 Sep 2020 04:05:10
User entered 'None (1)'	System	04 Sep 2020 04:05:10

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:05:05', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '02af94a6-16c2-4fc4-aae4-27e3b9b696c2'	System	04 Sep 2020 04:05:10
User entered '03 Sep 2020 23:05'	System	04 Sep 2020 04:05:10

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 3'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-09-05T08:38:30', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'b832d9dd-7620-49bb-9031-ea7ddbde44ea'	System	05 Sep 2020 13:38:59
User entered 'None (1)'	System	05 Sep 2020 13:38:59

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:38:34', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'b832d9dd-7620-49bb-9031-ea7ddbde44ea'	System	05 Sep 2020 13:38:59
User entered 'No (N)'	System	05 Sep 2020 13:38:59

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:38:38', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'b832d9dd-7620-49bb-9031-ea7ddbde44ea'	System	05 Sep 2020 13:38:59
User entered 'No (N)'	System	05 Sep 2020 13:38:59

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-09-05T08:38:46', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'b832d9dd-7620-49bb-9031-ea7ddbde44ea'	System	05 Sep 2020 13:38:59
User entered 'None (1)'	System	05 Sep 2020 13:38:59

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:38:53', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'b832d9dd-7620-49bb-9031-ea7ddbde44ea'	System	05 Sep 2020 13:38:59
User entered '05 Sep 2020 08:38'	System	05 Sep 2020 13:38:59

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 4'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-09-05T23:24:02', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6ada6734-ca6e-41a8-ac2b-43631aa4aa78'	System	06 Sep 2020 04:24:22
User entered 'None (1)'	System	06 Sep 2020 04:24:22

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:05', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6ada6734-ca6e-41a8-ac2b-43631aa4aa78'	System	06 Sep 2020 04:24:22
User entered 'No (N)'	System	06 Sep 2020 04:24:22

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:08', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6ada6734-ca6e-41a8-ac2b-43631aa4aa78'	System	06 Sep 2020 04:24:22
User entered 'No (N)'	System	06 Sep 2020 04:24:22

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-09-05T23:24:15', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6ada6734-ca6e-41a8-ac2b-43631aa4aa78'	System	06 Sep 2020 04:24:22
User entered 'None (1)'	System	06 Sep 2020 04:24:22

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:18', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6ada6734-ca6e-41a8-ac2b-43631aa4aa78'	System	06 Sep 2020 04:24:22
User entered '05 Sep 2020 23:24'	System	06 Sep 2020 04:24:22

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 5'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-09-07T00:04:33', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '97945944-d5f5-461d-8de3-0eef58763301'	System	07 Sep 2020 05:04:51
User entered 'None (1)'	System	07 Sep 2020 05:04:51

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:37', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '97945944-d5f5-461d-8de3-0eef58763301'	System	07 Sep 2020 05:04:51
User entered 'No (N)'	System	07 Sep 2020 05:04:51

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:40', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '97945944-d5f5-461d-8de3-0eef58763301'	System	07 Sep 2020 05:04:51
User entered 'No (N)'	System	07 Sep 2020 05:04:51

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-09-07T00:04:44', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '97945944-d5f5-461d-8de3-0eef58763301'	System	07 Sep 2020 05:04:51
User entered 'None (1)'	System	07 Sep 2020 05:04:51

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:47', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '97945944-d5f5-461d-8de3-0eef58763301'	System	07 Sep 2020 05:04:51
User entered '07 Sep 2020 00:04'	System	07 Sep 2020 05:04:51

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 6'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-09-07T21:37:10', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'de19a42b-af8a-4ca3-8f90-4bbb3f67659c'	System	08 Sep 2020 02:37:45
User entered 'None (1)'	System	08 Sep 2020 02:37:45

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:37:15', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'de19a42b-af8a-4ca3-8f90-4bbb3f67659c'	System	08 Sep 2020 02:37:45
User entered 'No (N)'	System	08 Sep 2020 02:37:45

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:37:27', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'de19a42b-af8a-4ca3-8f90-4bbb3f67659c'	System	08 Sep 2020 02:37:45
User entered 'No (N)'	System	08 Sep 2020 02:37:45

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-09-07T21:37:33', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'de19a42b-af8a-4ca3-8f90-4bbb3f67659c'	System	08 Sep 2020 02:37:45
User entered 'None (1)'	System	08 Sep 2020 02:37:45

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:37:41', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'de19a42b-af8a-4ca3-8f90-4bbb3f67659c'	System	08 Sep 2020 02:37:45
User entered '07 Sep 2020 21:37'	System	08 Sep 2020 02:37:45

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 7'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-09-08T21:00:24', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '2ceb9f45-e484-4610-9779-9c46549aedb8'	System	09 Sep 2020 02:00:55
User entered 'None (1)'	System	09 Sep 2020 02:00:55

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:00:28', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '2ceb9f45-e484-4610-9779-9c46549aedb8'	System	09 Sep 2020 02:00:55
User entered 'No (N)'	System	09 Sep 2020 02:00:55

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:00:34', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '2ceb9f45-e484-4610-9779-9c46549aedb8'	System	09 Sep 2020 02:00:55
User entered 'No (N)'	System	09 Sep 2020 02:00:55

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-09-08T21:00:42', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '2ceb9f45-e484-4610-9779-9c46549aedb8'	System	09 Sep 2020 02:00:55
User entered 'None (1)'	System	09 Sep 2020 02:00:55

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:00:53', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '2ceb9f45-e484-4610-9779-9c46549aedb8'	System	09 Sep 2020 02:00:55
User entered '08 Sep 2020 21:00'	System	09 Sep 2020 02:00:55

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:01:14', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '64974edf-cbba-4557-a10c-479362e1fc68'	System	02 Sep 2020 23:02:23
User entered 'None (0)'	System	02 Sep 2020 23:02:23

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:01:26', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '64974edf-cbba-4557-a10c-479362e1fc68'	System	02 Sep 2020 23:02:23
User entered 'None (0)'	System	02 Sep 2020 23:02:23

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:01:33', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '64974edf-cbba-4557-a10c-479362e1fc68'	System	02 Sep 2020 23:02:23
User entered 'None (0)'	System	02 Sep 2020 23:02:23

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:01:48', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '64974edf-cbba-4557-a10c-479362e1fc68'	System	02 Sep 2020 23:02:23
User entered 'None (0)'	System	02 Sep 2020 23:02:23

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:01:57', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '64974edf-cbba-4557-a10c-479362e1fc68'	System	02 Sep 2020 23:02:23
User entered 'None (0)'	System	02 Sep 2020 23:02:23

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:02:02', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '64974edf-cbba-4557-a10c-479362e1fc68'	System	02 Sep 2020 23:02:23
User entered 'None (0)'	System	02 Sep 2020 23:02:23

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

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 (925f6005fee9c9e7)', Time: '2020-09-02T18:02:11', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '64974edf-cbba-4557-a10c-479362e1fc68'	System	02 Sep 2020 23:02:23
User entered 'No (N)'	System	02 Sep 2020 23:02:23

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T18:02:18', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '64974edf-cbba-4557-a10c-479362e1fc68'	System	02 Sep 2020 23:02:23
User entered '02 Sep 2020 18:02'	System	02 Sep 2020 23:02:23

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 17:41'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 20:11'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:29:10', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f55805f8-69c2-4dd2-98d1-3619bf767c8a'	System	03 Sep 2020 03:29:42
User entered 'None (0)'	System	03 Sep 2020 03:29:42

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:29:14', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f55805f8-69c2-4dd2-98d1-3619bf767c8a'	System	03 Sep 2020 03:29:42
User entered 'None (0)'	System	03 Sep 2020 03:29:42

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:29:18', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f55805f8-69c2-4dd2-98d1-3619bf767c8a'	System	03 Sep 2020 03:29:42
User entered 'None (0)'	System	03 Sep 2020 03:29:42

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:29:22', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f55805f8-69c2-4dd2-98d1-3619bf767c8a'	System	03 Sep 2020 03:29:42
User entered 'None (0)'	System	03 Sep 2020 03:29:42

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:29:26', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f55805f8-69c2-4dd2-98d1-3619bf767c8a'	System	03 Sep 2020 03:29:42
User entered 'None (0)'	System	03 Sep 2020 03:29:42

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:29:29', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f55805f8-69c2-4dd2-98d1-3619bf767c8a'	System	03 Sep 2020 03:29:42
User entered 'None (0)'	System	03 Sep 2020 03:29:42

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

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 (925f6005fee9c9e7)', Time: '2020-09-02T22:29:36', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f55805f8-69c2-4dd2-98d1-3619bf767c8a'	System	03 Sep 2020 03:29:42
User entered 'No (N)'	System	03 Sep 2020 03:29:42

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-02T22:29:39', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f55805f8-69c2-4dd2-98d1-3619bf767c8a'	System	03 Sep 2020 03:29:42
User entered '02 Sep 2020 22:29'	System	03 Sep 2020 03:29:42

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 21:06'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 2'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:05:20', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c3d916e6-726b-4a0d-a0b2-8d8fbc821c54'	System	04 Sep 2020 04:06:01
User entered 'None (0)'	System	04 Sep 2020 04:06:01

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:05:28', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c3d916e6-726b-4a0d-a0b2-8d8fbc821c54'	System	04 Sep 2020 04:06:01
User entered 'None (0)'	System	04 Sep 2020 04:06:01

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:05:31', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c3d916e6-726b-4a0d-a0b2-8d8fbc821c54'	System	04 Sep 2020 04:06:01
User entered 'None (0)'	System	04 Sep 2020 04:06:01

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:05:38', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c3d916e6-726b-4a0d-a0b2-8d8fbc821c54'	System	04 Sep 2020 04:06:01
User entered 'None (0)'	System	04 Sep 2020 04:06:01

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:05:41', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c3d916e6-726b-4a0d-a0b2-8d8fbc821c54'	System	04 Sep 2020 04:06:01
User entered 'None (0)'	System	04 Sep 2020 04:06:01

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:05:45', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c3d916e6-726b-4a0d-a0b2-8d8fbc821c54'	System	04 Sep 2020 04:06:01
User entered 'None (0)'	System	04 Sep 2020 04:06:01

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

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 (925f6005fee9c9e7)', Time: '2020-09-03T23:05:53', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c3d916e6-726b-4a0d-a0b2-8d8fbc821c54'	System	04 Sep 2020 04:06:01
User entered 'No (N)'	System	04 Sep 2020 04:06:01

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-03T23:05:56', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c3d916e6-726b-4a0d-a0b2-8d8fbc821c54'	System	04 Sep 2020 04:06:01
User entered '03 Sep 2020 23:05'	System	04 Sep 2020 04:06:01

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 3'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:38:58', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '326b789a-620e-43c9-9206-ff2e3183a737'	System	05 Sep 2020 13:39:26
User entered 'None (0)'	System	05 Sep 2020 13:39:26

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:39:01', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '326b789a-620e-43c9-9206-ff2e3183a737'	System	05 Sep 2020 13:39:26
User entered 'None (0)'	System	05 Sep 2020 13:39:26

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:39:07', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '326b789a-620e-43c9-9206-ff2e3183a737'	System	05 Sep 2020 13:39:26
User entered 'None (0)'	System	05 Sep 2020 13:39:26

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:39:11', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '326b789a-620e-43c9-9206-ff2e3183a737'	System	05 Sep 2020 13:39:26
User entered 'None (0)'	System	05 Sep 2020 13:39:26

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:39:13', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '326b789a-620e-43c9-9206-ff2e3183a737'	System	05 Sep 2020 13:39:26
User entered 'None (0)'	System	05 Sep 2020 13:39:26

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:39:16', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '326b789a-620e-43c9-9206-ff2e3183a737'	System	05 Sep 2020 13:39:26
User entered 'None (0)'	System	05 Sep 2020 13:39:26

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

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 (925f6005fee9c9e7)', Time: '2020-09-05T08:39:20', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '326b789a-620e-43c9-9206-ff2e3183a737'	System	05 Sep 2020 13:39:26
User entered 'No (N)'	System	05 Sep 2020 13:39:26

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T08:39:22', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '326b789a-620e-43c9-9206-ff2e3183a737'	System	05 Sep 2020 13:39:26
User entered '05 Sep 2020 08:39'	System	05 Sep 2020 13:39:26

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 4'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:24', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '49c2b904-422f-43a4-be17-948f6e8fc3f9'	System	06 Sep 2020 04:24:51
User entered 'None (0)'	System	06 Sep 2020 04:24:51

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:26', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '49c2b904-422f-43a4-be17-948f6e8fc3f9'	System	06 Sep 2020 04:24:51
User entered 'None (0)'	System	06 Sep 2020 04:24:51

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:29', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '49c2b904-422f-43a4-be17-948f6e8fc3f9'	System	06 Sep 2020 04:24:51
User entered 'None (0)'	System	06 Sep 2020 04:24:51

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:31', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '49c2b904-422f-43a4-be17-948f6e8fc3f9'	System	06 Sep 2020 04:24:51
User entered 'None (0)'	System	06 Sep 2020 04:24:51

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:34', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '49c2b904-422f-43a4-be17-948f6e8fc3f9'	System	06 Sep 2020 04:24:51
User entered 'None (0)'	System	06 Sep 2020 04:24:51

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:37', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '49c2b904-422f-43a4-be17-948f6e8fc3f9'	System	06 Sep 2020 04:24:51
User entered 'None (0)'	System	06 Sep 2020 04:24:51

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

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 (925f6005fee9c9e7)', Time: '2020-09-05T23:24:44', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '49c2b904-422f-43a4-be17-948f6e8fc3f9'	System	06 Sep 2020 04:24:51
User entered 'No (N)'	System	06 Sep 2020 04:24:51

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-05T23:24:47', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '49c2b904-422f-43a4-be17-948f6e8fc3f9'	System	06 Sep 2020 04:24:51
User entered '05 Sep 2020 23:24'	System	06 Sep 2020 04:24:51

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 5'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:52', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '88a1ba86-80c2-4c10-b17c-dd57b2ad84e4'	System	07 Sep 2020 05:05:16
User entered 'None (0)'	System	07 Sep 2020 05:05:16

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:55', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '88a1ba86-80c2-4c10-b17c-dd57b2ad84e4'	System	07 Sep 2020 05:05:16
User entered 'None (0)'	System	07 Sep 2020 05:05:16

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:04:57', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '88a1ba86-80c2-4c10-b17c-dd57b2ad84e4'	System	07 Sep 2020 05:05:16
User entered 'None (0)'	System	07 Sep 2020 05:05:16

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:05:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '88a1ba86-80c2-4c10-b17c-dd57b2ad84e4'	System	07 Sep 2020 05:05:16
User entered 'None (0)'	System	07 Sep 2020 05:05:16

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:05:03', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '88a1ba86-80c2-4c10-b17c-dd57b2ad84e4'	System	07 Sep 2020 05:05:16
User entered 'None (0)'	System	07 Sep 2020 05:05:16

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:05:05', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '88a1ba86-80c2-4c10-b17c-dd57b2ad84e4'	System	07 Sep 2020 05:05:16
User entered 'None (0)'	System	07 Sep 2020 05:05:16

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:26

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 (925f6005fee9c9e7)', Time: '2020-09-07T00:05:09', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '88a1ba86-80c2-4c10-b17c-dd57b2ad84e4'	System	07 Sep 2020 05:05:16
User entered 'No (N)'	System	07 Sep 2020 05:05:16

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T00:05:11', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '88a1ba86-80c2-4c10-b17c-dd57b2ad84e4'	System	07 Sep 2020 05:05:16
User entered '07 Sep 2020 00:05'	System	07 Sep 2020 05:05:16

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 6'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:37:52', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f3c8cd4a-596a-4698-9e18-f4d1f5072505'	System	08 Sep 2020 02:39:33
User entered 'None (0)'	System	08 Sep 2020 02:39:33

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:38:07', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f3c8cd4a-596a-4698-9e18-f4d1f5072505'	System	08 Sep 2020 02:39:33
User entered 'None (0)'	System	08 Sep 2020 02:39:33

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:38:26', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f3c8cd4a-596a-4698-9e18-f4d1f5072505'	System	08 Sep 2020 02:39:33
User entered 'None (0)'	System	08 Sep 2020 02:39:33

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:38:30', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f3c8cd4a-596a-4698-9e18-f4d1f5072505'	System	08 Sep 2020 02:39:33
User entered 'None (0)'	System	08 Sep 2020 02:39:33

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:38:45', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f3c8cd4a-596a-4698-9e18-f4d1f5072505'	System	08 Sep 2020 02:39:33
User entered 'None (0)'	System	08 Sep 2020 02:39:33

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:39:20', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f3c8cd4a-596a-4698-9e18-f4d1f5072505'	System	08 Sep 2020 02:39:33
User entered 'Some interference with activity not requiring medical attention (2)'	System	08 Sep 2020 02:39:33

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

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 (925f6005fee9c9e7)', Time: '2020-09-07T21:39:26', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f3c8cd4a-596a-4698-9e18-f4d1f5072505'	System	08 Sep 2020 02:39:33
User entered 'No (N)'	System	08 Sep 2020 02:39:33

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-07T21:39:30', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f3c8cd4a-596a-4698-9e18-f4d1f5072505'	System	08 Sep 2020 02:39:33
User entered '07 Sep 2020 21:39'	System	08 Sep 2020 02:39:33

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 7'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:01:04', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4216978a-4912-4e64-b7f0-2c55715a9305'	System	09 Sep 2020 02:01:48
User entered 'None (0)'	System	09 Sep 2020 02:01:48

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:01:14', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4216978a-4912-4e64-b7f0-2c55715a9305'	System	09 Sep 2020 02:01:48
User entered 'None (0)'	System	09 Sep 2020 02:01:48

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:01:19', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4216978a-4912-4e64-b7f0-2c55715a9305'	System	09 Sep 2020 02:01:48
User entered 'None (0)'	System	09 Sep 2020 02:01:48

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:01:25', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4216978a-4912-4e64-b7f0-2c55715a9305'	System	09 Sep 2020 02:01:48
User entered 'None (0)'	System	09 Sep 2020 02:01:48

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:01:29', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4216978a-4912-4e64-b7f0-2c55715a9305'	System	09 Sep 2020 02:01:48
User entered 'None (0)'	System	09 Sep 2020 02:01:48

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:01:36', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4216978a-4912-4e64-b7f0-2c55715a9305'	System	09 Sep 2020 02:01:48
User entered 'None (0)'	System	09 Sep 2020 02:01:48

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

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 (925f6005fee9c9e7)', Time: '2020-09-08T21:01:40', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4216978a-4912-4e64-b7f0-2c55715a9305'	System	09 Sep 2020 02:01:48
User entered 'No (N)'	System	09 Sep 2020 02:01:48

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-08T21:01:43', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4216978a-4912-4e64-b7f0-2c55715a9305'	System	09 Sep 2020 02:01:48
User entered '08 Sep 2020 21:01'	System	09 Sep 2020 02:01:48

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:57:31

US3012263

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:17:52

US3012263

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 05:18:53
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'correct as entered' (Site from System).	Katherine Davis (b) (4)	16 Sep 2020 20:17:59
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Sep 2020 20:17:52
User entered '16 Sep 2020'	Katherine Davis (b) (4)	16 Sep 2020 20:17:52

US3012263

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:17:52

US3012263

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:17:52

US3012263

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:18:05

US3012263

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Sep 2020 20:18:05

US3012263

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:24:51

US3012263

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Sep 2020 22:25:08
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	25 Sep 2020 22:25:08
User entered '18 Sep 2020' reason for change: Data Entry Error	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:25:08
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Sep 2020 22:24:51
User entered '25 Sep 2020'	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:24:51

US3012263

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:24:51

US3012263

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:24:51

US3012263

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:25:13

US3012263

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Sep 2020 22:25:13

US3012263

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:25:49

US3012263

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:25:49

US3012263

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:25:49

US3012263

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:25:49

US3012263

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	25 Sep 2020 22:25:52

US3012263

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Sep 2020 22:25:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:06:28

US3012263

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:06:28

US3012263

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:06:28

US3012263

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	30 Sep 2020 23:06:28

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '14:04'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 14:04'	System	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '94'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '18'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '127'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 23:07:14

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '17:54'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 17:54'	System	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '81'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '14'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '104'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '66'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 23:07:52

US3012263

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:26

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:08:02

US3012263

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:08:02

US3012263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 22:48:10

US3012263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 22:48:10

US3012263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 22:48:10

US3012263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 22:48:10

US3012263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 22:48:10

US3012263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '17:15'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 22:48:10

US3012263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 17:15'	System	30 Sep 2020 22:48:10

US3012263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 22:48:10

US3012263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	30 Sep 2020 22:48:10

US3012263

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 22:48:10

US3012263

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:08:25

US3012263

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:08:25

US3012263

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '16:30' reason for change: Data Entry Error	Katherine Davis (b) (4)	30 Sep 2020 23:08:43
User entered '16:20'	Katherine Davis (b) (4)	30 Sep 2020 23:08:25

US3012263

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 16:30'	System	30 Sep 2020 23:08:43
User entered '30 Sep 2020 16:20'	System	30 Sep 2020 23:08:25

US3012263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:43:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:09:06

US3012263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:26

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Katherine Davis (b) (4)	30 Sep 2020 23:09:06

US3012263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:09:06

US3012263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '16:20'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:09:06

US3012263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 16:20'	System	30 Sep 2020 23:09:06

US3012263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:26

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Katherine Davis (b) (4)	30 Sep 2020 23:09:06

US3012263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:09:06

US3012263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:09:06

US3012263

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 23:09:06

US3012263

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	30 Sep 2020 23:09:12

US3012263

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 23:09:12

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:49:14', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '01408fd2-037f-4844-ab4f-4cdd18cff8d9'	System	30 Sep 2020 22:49:46
User entered 'Yes (Y)'	System	30 Sep 2020 22:49:46

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:49:24', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '01408fd2-037f-4844-ab4f-4cdd18cff8d9'	System	30 Sep 2020 22:49:46
User entered '98.1'	System	30 Sep 2020 22:49:46

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:49:35', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '01408fd2-037f-4844-ab4f-4cdd18cff8d9'	System	30 Sep 2020 22:49:46
User entered 'No (N)'	System	30 Sep 2020 22:49:46

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:49:40', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '01408fd2-037f-4844-ab4f-4cdd18cff8d9'	System	30 Sep 2020 22:49:46
User entered '30 Sep 2020 17:49'	System	30 Sep 2020 22:49:46

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 17:35'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 20:05'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:16:55', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f60b5f87-be6d-4028-8cf7-b644cd7c3a8c'	System	01 Oct 2020 03:18:57
User entered 'Yes (Y)'	System	01 Oct 2020 03:18:57

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:18:40', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f60b5f87-be6d-4028-8cf7-b644cd7c3a8c'	System	01 Oct 2020 03:18:57
User entered '95.3'	System	01 Oct 2020 03:18:57

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:18:48', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f60b5f87-be6d-4028-8cf7-b644cd7c3a8c'	System	01 Oct 2020 03:18:57
User entered 'No (N)'	System	01 Oct 2020 03:18:57

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:18:53', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'f60b5f87-be6d-4028-8cf7-b644cd7c3a8c'	System	01 Oct 2020 03:18:57
User entered '30 Sep 2020 22:18'	System	01 Oct 2020 03:18:57

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 21:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 2'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:09:43', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ccee60fd-b636-4103-a4a1-c932697e57ed'	System	02 Oct 2020 06:12:02
User entered 'Yes (Y)'	System	02 Oct 2020 06:12:02

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:11:47', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ccee60fd-b636-4103-a4a1-c932697e57ed'	System	02 Oct 2020 06:12:02
User entered '96.4'	System	02 Oct 2020 06:12:02

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:11:55', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ccee60fd-b636-4103-a4a1-c932697e57ed'	System	02 Oct 2020 06:12:02
User entered 'No (N)'	System	02 Oct 2020 06:12:02

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:11:59', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ccee60fd-b636-4103-a4a1-c932697e57ed'	System	02 Oct 2020 06:12:02
User entered '02 Oct 2020 01:11'	System	02 Oct 2020 06:12:02

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 3'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:48:27', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4c095c41-e03a-42d4-8ad4-0c0b3b8bcf85'	System	03 Oct 2020 03:49:18
User entered 'Yes (Y)'	System	03 Oct 2020 03:49:18

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:48:40', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4c095c41-e03a-42d4-8ad4-0c0b3b8bcf85'	System	03 Oct 2020 03:49:18
User entered '96.0'	System	03 Oct 2020 03:49:18

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:26

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:48:57', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4c095c41-e03a-42d4-8ad4-0c0b3b8bcf85'	System	03 Oct 2020 03:49:18
User entered 'No (N)'	System	03 Oct 2020 03:49:18

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:49:17', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '4c095c41-e03a-42d4-8ad4-0c0b3b8bcf85'	System	03 Oct 2020 03:49:18
User entered '02 Oct 2020 22:49'	System	03 Oct 2020 03:49:18

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 4'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-03T23:58:59', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1ec18452-1969-49ce-a33e-c29d082b6554'	System	04 Oct 2020 05:02:14
User entered 'Yes (Y)'	System	04 Oct 2020 05:02:14

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:01:37', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1ec18452-1969-49ce-a33e-c29d082b6554'	System	04 Oct 2020 05:02:14
User entered '96.0'	System	04 Oct 2020 05:02:14

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:01:46', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1ec18452-1969-49ce-a33e-c29d082b6554'	System	04 Oct 2020 05:02:14
User entered 'No (N)'	System	04 Oct 2020 05:02:14

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:01:50', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1ec18452-1969-49ce-a33e-c29d082b6554'	System	04 Oct 2020 05:02:14
User entered '04 Oct 2020 00:01'	System	04 Oct 2020 05:02:14

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 5'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 6'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:51:52', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '2c8e2c6d-674c-4081-9323-732de40fd4c1'	System	06 Oct 2020 05:52:13
User entered 'Yes (Y)'	System	06 Oct 2020 05:52:13

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:01', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '2c8e2c6d-674c-4081-9323-732de40fd4c1'	System	06 Oct 2020 05:52:13
User entered '96.4'	System	06 Oct 2020 05:52:13

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:05', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '2c8e2c6d-674c-4081-9323-732de40fd4c1'	System	06 Oct 2020 05:52:13
User entered 'No (N)'	System	06 Oct 2020 05:52:13

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:10', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '2c8e2c6d-674c-4081-9323-732de40fd4c1'	System	06 Oct 2020 05:52:13
User entered '06 Oct 2020 00:52'	System	06 Oct 2020 05:52:13

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 7'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:52:21', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6c9ce927-30de-4fa6-b9aa-fd14629b2734'	System	07 Oct 2020 02:53:01
User entered 'Yes (Y)'	System	07 Oct 2020 02:53:01

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:52:30', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6c9ce927-30de-4fa6-b9aa-fd14629b2734'	System	07 Oct 2020 02:53:01
User entered '95.5'	System	07 Oct 2020 02:53:01

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:52:52', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6c9ce927-30de-4fa6-b9aa-fd14629b2734'	System	07 Oct 2020 02:53:01
User entered 'No (N)'	System	07 Oct 2020 02:53:01

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:52:58', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '6c9ce927-30de-4fa6-b9aa-fd14629b2734'	System	07 Oct 2020 02:53:01
User entered '06 Oct 2020 21:52'	System	07 Oct 2020 02:53:01

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-09-30T17:49:49', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c0294395-8971-44ef-af2c-08b27bae9cd4'	System	30 Sep 2020 22:50:22
User entered 'None (1)'	System	30 Sep 2020 22:50:22

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:49:59', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c0294395-8971-44ef-af2c-08b27bae9cd4'	System	30 Sep 2020 22:50:22
User entered 'No (N)'	System	30 Sep 2020 22:50:22

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:06', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c0294395-8971-44ef-af2c-08b27bae9cd4'	System	30 Sep 2020 22:50:22
User entered 'No (N)'	System	30 Sep 2020 22:50:22

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-09-30T17:50:11', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c0294395-8971-44ef-af2c-08b27bae9cd4'	System	30 Sep 2020 22:50:22
User entered 'None (1)'	System	30 Sep 2020 22:50:22

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:19', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'c0294395-8971-44ef-af2c-08b27bae9cd4'	System	30 Sep 2020 22:50:22
User entered '30 Sep 2020 17:50'	System	30 Sep 2020 22:50:22

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 17:35'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 20:05'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-09-30T22:18:59', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1479d1a8-a00f-4c96-8ae5-aca6b3e36a47'	System	01 Oct 2020 03:19:16
User entered 'None (1)'	System	01 Oct 2020 03:19:16

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:03', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1479d1a8-a00f-4c96-8ae5-aca6b3e36a47'	System	01 Oct 2020 03:19:16
User entered 'No (N)'	System	01 Oct 2020 03:19:16

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:07', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1479d1a8-a00f-4c96-8ae5-aca6b3e36a47'	System	01 Oct 2020 03:19:16
User entered 'No (N)'	System	01 Oct 2020 03:19:16

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-09-30T22:19:10', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1479d1a8-a00f-4c96-8ae5-aca6b3e36a47'	System	01 Oct 2020 03:19:16
User entered 'None (1)'	System	01 Oct 2020 03:19:16

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:13', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '1479d1a8-a00f-4c96-8ae5-aca6b3e36a47'	System	01 Oct 2020 03:19:16
User entered '30 Sep 2020 22:19'	System	01 Oct 2020 03:19:16

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 21:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 2'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-10-02T01:12:05', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'acc963c2-f5bc-4278-8a6c-5c5133481f97'	System	02 Oct 2020 06:12:24
User entered 'None (1)'	System	02 Oct 2020 06:12:24

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:08', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'acc963c2-f5bc-4278-8a6c-5c5133481f97'	System	02 Oct 2020 06:12:24
User entered 'No (N)'	System	02 Oct 2020 06:12:24

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:12', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'acc963c2-f5bc-4278-8a6c-5c5133481f97'	System	02 Oct 2020 06:12:24
User entered 'No (N)'	System	02 Oct 2020 06:12:24

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-10-02T01:12:19', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'acc963c2-f5bc-4278-8a6c-5c5133481f97'	System	02 Oct 2020 06:12:24
User entered 'None (1)'	System	02 Oct 2020 06:12:24

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:23', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'acc963c2-f5bc-4278-8a6c-5c5133481f97'	System	02 Oct 2020 06:12:24
User entered '02 Oct 2020 01:12'	System	02 Oct 2020 06:12:24

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 3'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-10-02T22:49:23', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '9f0a5fd0-78f2-40cd-860e-e981cacdbf10'	System	03 Oct 2020 03:50:01
User entered 'None (1)'	System	03 Oct 2020 03:50:01

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:49:39', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '9f0a5fd0-78f2-40cd-860e-e981cacdbf10'	System	03 Oct 2020 03:50:01
User entered 'No (N)'	System	03 Oct 2020 03:50:01

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:49:43', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '9f0a5fd0-78f2-40cd-860e-e981cacdbf10'	System	03 Oct 2020 03:50:01
User entered 'No (N)'	System	03 Oct 2020 03:50:01

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-10-02T22:49:48', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '9f0a5fd0-78f2-40cd-860e-e981cacdbf10'	System	03 Oct 2020 03:50:01
User entered 'None (1)'	System	03 Oct 2020 03:50:01

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:49:58', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '9f0a5fd0-78f2-40cd-860e-e981cacdbf10'	System	03 Oct 2020 03:50:01
User entered '02 Oct 2020 22:49'	System	03 Oct 2020 03:50:01

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 4'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-10-04T00:01:57', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0553d57c-64ab-498d-ab7e-15813f8673af'	System	04 Oct 2020 05:02:48
User entered 'None (1)'	System	04 Oct 2020 05:02:48

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:00', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0553d57c-64ab-498d-ab7e-15813f8673af'	System	04 Oct 2020 05:02:48
User entered 'No (N)'	System	04 Oct 2020 05:02:48

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:04', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0553d57c-64ab-498d-ab7e-15813f8673af'	System	04 Oct 2020 05:02:48
User entered 'No (N)'	System	04 Oct 2020 05:02:48

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-10-04T00:02:09', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0553d57c-64ab-498d-ab7e-15813f8673af'	System	04 Oct 2020 05:02:48
User entered 'None (1)'	System	04 Oct 2020 05:02:48

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:19', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0553d57c-64ab-498d-ab7e-15813f8673af'	System	04 Oct 2020 05:02:48
User entered '04 Oct 2020 00:02'	System	04 Oct 2020 05:02:48

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 5'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 6'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-10-06T00:52:14', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '50cbd953-9cef-426f-9d3f-7420d2e7ac04'	System	06 Oct 2020 05:52:34
User entered 'None (1)'	System	06 Oct 2020 05:52:34

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:18', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '50cbd953-9cef-426f-9d3f-7420d2e7ac04'	System	06 Oct 2020 05:52:34
User entered 'No (N)'	System	06 Oct 2020 05:52:34

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:22', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '50cbd953-9cef-426f-9d3f-7420d2e7ac04'	System	06 Oct 2020 05:52:34
User entered 'No (N)'	System	06 Oct 2020 05:52:34

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-10-06T00:52:26', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '50cbd953-9cef-426f-9d3f-7420d2e7ac04'	System	06 Oct 2020 05:52:34
User entered 'None (1)'	System	06 Oct 2020 05:52:34

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:31', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '50cbd953-9cef-426f-9d3f-7420d2e7ac04'	System	06 Oct 2020 05:52:34
User entered '06 Oct 2020 00:52'	System	06 Oct 2020 05:52:34

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 7'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-10-06T21:53:06', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0138fa85-5e7e-4702-81df-540137bf09e8'	System	07 Oct 2020 02:53:26
User entered 'None (1)'	System	07 Oct 2020 02:53:26

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:10', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0138fa85-5e7e-4702-81df-540137bf09e8'	System	07 Oct 2020 02:53:26
User entered 'No (N)'	System	07 Oct 2020 02:53:26

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:13', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0138fa85-5e7e-4702-81df-540137bf09e8'	System	07 Oct 2020 02:53:26
User entered 'No (N)'	System	07 Oct 2020 02:53:26

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-10-06T21:53:18', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0138fa85-5e7e-4702-81df-540137bf09e8'	System	07 Oct 2020 02:53:26
User entered 'None (1)'	System	07 Oct 2020 02:53:26

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:21', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0138fa85-5e7e-4702-81df-540137bf09e8'	System	07 Oct 2020 02:53:26
User entered '06 Oct 2020 21:53'	System	07 Oct 2020 02:53:26

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:26', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dce8ed39-0fd2-4e3b-8d1e-3551bb72fb59'	System	30 Sep 2020 22:51:01
User entered 'None (0)'	System	30 Sep 2020 22:51:01

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:30', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dce8ed39-0fd2-4e3b-8d1e-3551bb72fb59'	System	30 Sep 2020 22:51:01
User entered 'None (0)'	System	30 Sep 2020 22:51:01

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:34', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dce8ed39-0fd2-4e3b-8d1e-3551bb72fb59'	System	30 Sep 2020 22:51:01
User entered 'None (0)'	System	30 Sep 2020 22:51:01

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:40', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dce8ed39-0fd2-4e3b-8d1e-3551bb72fb59'	System	30 Sep 2020 22:51:01
User entered 'None (0)'	System	30 Sep 2020 22:51:01

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:43', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dce8ed39-0fd2-4e3b-8d1e-3551bb72fb59'	System	30 Sep 2020 22:51:01
User entered 'None (0)'	System	30 Sep 2020 22:51:01

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:46', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dce8ed39-0fd2-4e3b-8d1e-3551bb72fb59'	System	30 Sep 2020 22:51:01
User entered 'None (0)'	System	30 Sep 2020 22:51:01

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

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 (925f6005fee9c9e7)', Time: '2020-09-30T17:50:51', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dce8ed39-0fd2-4e3b-8d1e-3551bb72fb59'	System	30 Sep 2020 22:51:01
User entered 'No (N)'	System	30 Sep 2020 22:51:01

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T17:50:59', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'dce8ed39-0fd2-4e3b-8d1e-3551bb72fb59'	System	30 Sep 2020 22:51:01
User entered '30 Sep 2020 17:50'	System	30 Sep 2020 22:51:01

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 17:35'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 20:05'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:19', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '61c58841-9703-4d47-9d08-52f791e354cb'	System	01 Oct 2020 03:19:48
User entered 'None (0)'	System	01 Oct 2020 03:19:48

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:22', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '61c58841-9703-4d47-9d08-52f791e354cb'	System	01 Oct 2020 03:19:48
User entered 'None (0)'	System	01 Oct 2020 03:19:48

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:25', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '61c58841-9703-4d47-9d08-52f791e354cb'	System	01 Oct 2020 03:19:48
User entered 'None (0)'	System	01 Oct 2020 03:19:48

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:30', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '61c58841-9703-4d47-9d08-52f791e354cb'	System	01 Oct 2020 03:19:48
User entered 'None (0)'	System	01 Oct 2020 03:19:48

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:33', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '61c58841-9703-4d47-9d08-52f791e354cb'	System	01 Oct 2020 03:19:48
User entered 'None (0)'	System	01 Oct 2020 03:19:48

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:36', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '61c58841-9703-4d47-9d08-52f791e354cb'	System	01 Oct 2020 03:19:48
User entered 'None (0)'	System	01 Oct 2020 03:19:48

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

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 (925f6005fee9c9e7)', Time: '2020-09-30T22:19:41', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '61c58841-9703-4d47-9d08-52f791e354cb'	System	01 Oct 2020 03:19:48
User entered 'No (N)'	System	01 Oct 2020 03:19:48

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-09-30T22:19:44', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '61c58841-9703-4d47-9d08-52f791e354cb'	System	01 Oct 2020 03:19:48
User entered '30 Sep 2020 22:19'	System	01 Oct 2020 03:19:48

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 21:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 2'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:30', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '911949b6-8a06-40a8-b819-20d28421b3a3'	System	02 Oct 2020 06:12:59
User entered 'None (0)'	System	02 Oct 2020 06:12:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:37', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '911949b6-8a06-40a8-b819-20d28421b3a3'	System	02 Oct 2020 06:12:59
User entered 'None (0)'	System	02 Oct 2020 06:12:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:41', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '911949b6-8a06-40a8-b819-20d28421b3a3'	System	02 Oct 2020 06:12:59
User entered 'None (0)'	System	02 Oct 2020 06:12:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:44', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '911949b6-8a06-40a8-b819-20d28421b3a3'	System	02 Oct 2020 06:12:59
User entered 'None (0)'	System	02 Oct 2020 06:12:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:47', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '911949b6-8a06-40a8-b819-20d28421b3a3'	System	02 Oct 2020 06:12:59
User entered 'None (0)'	System	02 Oct 2020 06:12:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:50', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '911949b6-8a06-40a8-b819-20d28421b3a3'	System	02 Oct 2020 06:12:59
User entered 'None (0)'	System	02 Oct 2020 06:12:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

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 (925f6005fee9c9e7)', Time: '2020-10-02T01:12:55', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '911949b6-8a06-40a8-b819-20d28421b3a3'	System	02 Oct 2020 06:12:59
User entered 'No (N)'	System	02 Oct 2020 06:12:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T01:12:57', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '911949b6-8a06-40a8-b819-20d28421b3a3'	System	02 Oct 2020 06:12:59
User entered '02 Oct 2020 01:12'	System	02 Oct 2020 06:12:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 3'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:50:10', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ca631f3a-7dcb-48d9-82b8-cddb4f6f3d2c'	System	03 Oct 2020 03:50:45
User entered 'None (0)'	System	03 Oct 2020 03:50:45

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:50:13', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ca631f3a-7dcb-48d9-82b8-cddb4f6f3d2c'	System	03 Oct 2020 03:50:45
User entered 'None (0)'	System	03 Oct 2020 03:50:45

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:50:22', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ca631f3a-7dcb-48d9-82b8-cddb4f6f3d2c'	System	03 Oct 2020 03:50:45
User entered 'None (0)'	System	03 Oct 2020 03:50:45

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:50:26', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ca631f3a-7dcb-48d9-82b8-cddb4f6f3d2c'	System	03 Oct 2020 03:50:45
User entered 'None (0)'	System	03 Oct 2020 03:50:45

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:50:29', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ca631f3a-7dcb-48d9-82b8-cddb4f6f3d2c'	System	03 Oct 2020 03:50:45
User entered 'None (0)'	System	03 Oct 2020 03:50:45

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:50:33', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ca631f3a-7dcb-48d9-82b8-cddb4f6f3d2c'	System	03 Oct 2020 03:50:45
User entered 'None (0)'	System	03 Oct 2020 03:50:45

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

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 (925f6005fee9c9e7)', Time: '2020-10-02T22:50:39', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ca631f3a-7dcb-48d9-82b8-cddb4f6f3d2c'	System	03 Oct 2020 03:50:45
User entered 'No (N)'	System	03 Oct 2020 03:50:45

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-02T22:50:43', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'ca631f3a-7dcb-48d9-82b8-cddb4f6f3d2c'	System	03 Oct 2020 03:50:45
User entered '02 Oct 2020 22:50'	System	03 Oct 2020 03:50:45

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 4'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:27', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '239e09e7-e607-4db0-9cfe-00656f737f66'	System	04 Oct 2020 05:03:12
User entered 'None (0)'	System	04 Oct 2020 05:03:12

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:30', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '239e09e7-e607-4db0-9cfe-00656f737f66'	System	04 Oct 2020 05:03:12
User entered 'None (0)'	System	04 Oct 2020 05:03:12

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:33', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '239e09e7-e607-4db0-9cfe-00656f737f66'	System	04 Oct 2020 05:03:12
User entered 'None (0)'	System	04 Oct 2020 05:03:12

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:36', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '239e09e7-e607-4db0-9cfe-00656f737f66'	System	04 Oct 2020 05:03:12
User entered 'None (0)'	System	04 Oct 2020 05:03:12

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:39', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '239e09e7-e607-4db0-9cfe-00656f737f66'	System	04 Oct 2020 05:03:12
User entered 'None (0)'	System	04 Oct 2020 05:03:12

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:42', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '239e09e7-e607-4db0-9cfe-00656f737f66'	System	04 Oct 2020 05:03:12
User entered 'None (0)'	System	04 Oct 2020 05:03:12

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

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 (925f6005fee9c9e7)', Time: '2020-10-04T00:02:47', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '239e09e7-e607-4db0-9cfe-00656f737f66'	System	04 Oct 2020 05:03:12
User entered 'No (N)'	System	04 Oct 2020 05:03:12

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-04T00:02:51', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '239e09e7-e607-4db0-9cfe-00656f737f66'	System	04 Oct 2020 05:03:12
User entered '04 Oct 2020 00:02'	System	04 Oct 2020 05:03:12

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 5'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 6'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:36', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '86712995-d9be-45ad-aebc-7fd60341ca35'	System	06 Oct 2020 05:52:59
User entered 'None (0)'	System	06 Oct 2020 05:52:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:39', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '86712995-d9be-45ad-aebc-7fd60341ca35'	System	06 Oct 2020 05:52:59
User entered 'None (0)'	System	06 Oct 2020 05:52:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:42', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '86712995-d9be-45ad-aebc-7fd60341ca35'	System	06 Oct 2020 05:52:59
User entered 'None (0)'	System	06 Oct 2020 05:52:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:45', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '86712995-d9be-45ad-aebc-7fd60341ca35'	System	06 Oct 2020 05:52:59
User entered 'None (0)'	System	06 Oct 2020 05:52:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:48', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '86712995-d9be-45ad-aebc-7fd60341ca35'	System	06 Oct 2020 05:52:59
User entered 'None (0)'	System	06 Oct 2020 05:52:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:50', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '86712995-d9be-45ad-aebc-7fd60341ca35'	System	06 Oct 2020 05:52:59
User entered 'None (0)'	System	06 Oct 2020 05:52:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

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 (925f6005fee9c9e7)', Time: '2020-10-06T00:52:55', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '86712995-d9be-45ad-aebc-7fd60341ca35'	System	06 Oct 2020 05:52:59
User entered 'No (N)'	System	06 Oct 2020 05:52:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T00:52:57', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '86712995-d9be-45ad-aebc-7fd60341ca35'	System	06 Oct 2020 05:52:59
User entered '06 Oct 2020 00:52'	System	06 Oct 2020 05:52:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 22:48:10
User entered 'Day 7'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:28', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '24715176-ebd7-45bc-9816-0cbc41315a37'	System	07 Oct 2020 02:53:59
User entered 'None (0)'	System	07 Oct 2020 02:53:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:31', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '24715176-ebd7-45bc-9816-0cbc41315a37'	System	07 Oct 2020 02:53:59
User entered 'None (0)'	System	07 Oct 2020 02:53:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:34', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '24715176-ebd7-45bc-9816-0cbc41315a37'	System	07 Oct 2020 02:53:59
User entered 'None (0)'	System	07 Oct 2020 02:53:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:39', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '24715176-ebd7-45bc-9816-0cbc41315a37'	System	07 Oct 2020 02:53:59
User entered 'None (0)'	System	07 Oct 2020 02:53:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:42', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '24715176-ebd7-45bc-9816-0cbc41315a37'	System	07 Oct 2020 02:53:59
User entered 'None (0)'	System	07 Oct 2020 02:53:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:45', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '24715176-ebd7-45bc-9816-0cbc41315a37'	System	07 Oct 2020 02:53:59
User entered 'None (0)'	System	07 Oct 2020 02:53:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

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 (925f6005fee9c9e7)', Time: '2020-10-06T21:53:50', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '24715176-ebd7-45bc-9816-0cbc41315a37'	System	07 Oct 2020 02:53:59
User entered 'No (N)'	System	07 Oct 2020 02:53:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-10-06T21:53:55', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '24715176-ebd7-45bc-9816-0cbc41315a37'	System	07 Oct 2020 02:53:59
User entered '06 Oct 2020 21:53'	System	07 Oct 2020 02:53:59

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 22:48:10

US3012263

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 22:48:10

US3012263

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	07 Oct 2020 17:30:14

US3012263

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '7 Oct 2020'	Tambra Dora (b) (4) (b) (4)	07 Oct 2020 17:30:14

US3012263

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	07 Oct 2020 17:30:14

US3012263

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	07 Oct 2020 17:30:14

US3012263

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	07 Oct 2020 17:30:17

US3012263

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Oct 2020 17:30:17

US3012263

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	14 Oct 2020 15:23:52

US3012263

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Tambra Dora (b) (4) (b) (4)	14 Oct 2020 15:23:52

US3012263

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	14 Oct 2020 15:23:52

US3012263

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	14 Oct 2020 15:23:52

US3012263

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	14 Oct 2020 15:23:56

US3012263

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Oct 2020 15:23:56

US3012263

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	21 Oct 2020 23:44:49

US3012263

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Tambra Dora (b) (4) (b) (4)	21 Oct 2020 23:44:49

US3012263

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	21 Oct 2020 23:44:49

US3012263

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	21 Oct 2020 23:44:49

US3012263

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	21 Oct 2020 23:44:53

US3012263

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Oct 2020 23:44:53

US3012263

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:29

US3012263

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:29

US3012263

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:29

US3012263

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:26

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	31 Oct 2020 00:05:29

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '15:55'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '30 Oct 2020 15:55'	System	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '97'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '16'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '139'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '82'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Oct 2020 00:05:56

US3012263

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:26

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:06:07

US3012263

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:06:07

US3012263

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:07:24

US3012263

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:07:24

US3012263

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:07'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:07:24

US3012263

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '30 Oct 2020 16:07'	System	31 Oct 2020 00:07:24

US3012263

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lamar Box (b) (4) (b) (4)	31 Oct 2020 00:07:28

US3012263

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Oct 2020 00:07:28

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered 'Day 78'	System	02 Sep 2020 22:57:31

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-11-17T13:00:42', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'bdf44b2a-2826-4725-89e5-0ca0640a5fb1'	System	17 Nov 2020 19:01:43
User entered 'Yes (Y)'	System	17 Nov 2020 19:01:43

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

Have you been exposed to someone with 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 (925f6005fee9c9e7)', Time: '2020-11-17T13:00:49', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'bdf44b2a-2826-4725-89e5-0ca0640a5fb1'	System	17 Nov 2020 19:01:43
User entered 'No (N)'	System	17 Nov 2020 19:01:43

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-11-17T13:00:56', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'bdf44b2a-2826-4725-89e5-0ca0640a5fb1'	System	17 Nov 2020 19:01:43
User entered 'No (N)'	System	17 Nov 2020 19:01:43

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-11-17T13:01:12', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'bdf44b2a-2826-4725-89e5-0ca0640a5fb1'	System	17 Nov 2020 19:01:43
User entered 'Yes (Y)'	System	17 Nov 2020 19:01:43

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-11-17T13:01:20', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'bdf44b2a-2826-4725-89e5-0ca0640a5fb1'	System	17 Nov 2020 19:01:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Nov 2020 19:01:43

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-11-17T13:01:30', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: 'bdf44b2a-2826-4725-89e5-0ca0640a5fb1'	System	17 Nov 2020 19:01:43
User entered '17 Nov 2020 13:01:30'	System	17 Nov 2020 19:01:43

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 22:57:31

US3012263

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 22:57:31
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 22:57:31

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '30 Oct 2020 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '03 Nov 2020 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '06 Nov 2020 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '10 Nov 2020 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '13 Nov 2020 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '17 Nov 2020 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[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 (925f6005fee9c9e7)', Time: '2020-11-23T10:30:13', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0e097370-0dcf-4831-8880-d6c9440e7289'	System	23 Nov 2020 16:30:27
User entered 'No (N)'	System	23 Nov 2020 16:30:27

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Have you been exposed to someone with 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 (925f6005fee9c9e7)', Time: '2020-11-23T10:30:18', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0e097370-0dcf-4831-8880-d6c9440e7289'	System	23 Nov 2020 16:30:27
User entered 'No (N)'	System	23 Nov 2020 16:30:27

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (925f6005fee9c9e7)', Time: '2020-11-23T10:30:24', User OID: 'PatientReportedOutcome (US3012263)', ODM File OID: '0e097370-0dcf-4831-8880-d6c9440e7289'	System	23 Nov 2020 16:30:27
User entered '23 Nov 2020 10:30:24'	System	23 Nov 2020 16:30:27

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:58:04

US3012263

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:58:04
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:58:04

US3012263

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 08:43:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:10:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Katherine Davis (b) (4)	16 Sep 2020 20:21:21
User entered 'No (N)'	Jennifer Leyva (b) (4)	02 Sep 2020 22:31:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental disorders NEC, PT: Loose tooth, LLT: Loose tooth - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 06:05:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 06:05:58
Data point term sent to Coder	System	16 Sep 2020 20:33:07
User entered 'LOOSE MOLAR' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	16 Sep 2020 20:32:51
Data point term sent to Coder	System	16 Sep 2020 20:22:47
User entered 'lose molar'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	16 Sep 2020 20:32:51
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Sep 2020 20:32:51
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4)	16 Sep 2020 20:32:51
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'start time unk ' (Site from System).	Katherine Davis (b) (4)	16 Sep 2020 20:27:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Sep 2020 20:27:33
User entered 'un:un' (non-conformant).	Katherine Davis (b) (4)	16 Sep 2020 20:27:33
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	16 Sep 2020 20:22:42
User entered '00:00'	Katherine Davis (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 20:32:51
User entered '15 Sep 2020 UN:UN' (non-conformant).	System	16 Sep 2020 20:27:33
User entered '15 Sep 2020 00:00'	System	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 02:30:59
User entered 'Yes (Y)'	Katherine Davis (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 20:27:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 20:27:33
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Katherine Davis (b) (4)	16 Sep 2020 20:27:33
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 20:22:42
User entered empty.	Katherine Davis (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 20:27:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 20:27:33
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Katherine Davis (b) (4)	16 Sep 2020 20:27:33
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 20:22:42
User entered empty.	Katherine Davis (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 20:27:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 20:27:33
User entered 'None (NONE)' reason for change: Data Entry Error	Katherine Davis (b) (4)	16 Sep 2020 20:27:33
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 20:22:42
User entered empty.	Katherine Davis (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[None](#)

Audit	User	Time (GMT)
User entered '1'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Narrative](#)

Audit	User	Time (GMT)
User entered 'MOLAR EXTRACTION DUE TO LOOSE MOLAR' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	16 Sep 2020 20:33:09
User entered 'molar extraction due to lose molar'	Katherine Davis (b) (4)	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Sep 2020 20:22:42

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:39:50
User entered 'USA-US006-2020-mRNA-1273-P301000003'	System	12 Nov 2020 16:28:37
User entered 'New'	(b) (4), (b) (6)	12 Nov 2020 16:28:37

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:04
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Gun shot wound, LLT: Gun shot wound - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 03:32:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 03:32:39
Data point term sent to Coder	System	11 Nov 2020 22:42:04
User entered 'Gunshot wound, right shoulder and spine'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:35
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:37
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:39
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:42
User entered '08 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:44
User entered empty.	Jennifer Leyva (b) (4)	11 Nov 2020 22:41:43
	(b) (4)	

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:46
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	11 Nov 2020 22:41:43
	(b) (4)	

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:52:25
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Per PI, will remain open until completely healed. No timeframe known.' (Site from Safety).	Jennifer Leyva (b) (4)	20 Nov 2020 19:05:55
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:01:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:47
User entered empty.	Jennifer Leyva (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:49
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:51
User entered 'Grade 4 (Grade 4)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:53
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:07:55
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:08
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 09:03:15
	(b) (4), (b) (6)	12 Nov 2020 16:08:17
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject is currently hospitalized. Discharge date is unknown.' (Site from System).	Jennifer Leyva (b) (4)	11 Nov 2020 22:43:52
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	11 Nov 2020 22:41:43
User entered 'I'	Jennifer Leyva (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:32
DataPoint Un-verified.	Jennifer Leyva (b) (4)	20 Nov 2020 19:12:39
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 19:12:39
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:22
User entered '08 Nov 2020'	Jennifer Leyva (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:52:30
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:43:43
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Updated' (Site from Safety).	Jennifer Leyva (b) (4)	20 Nov 2020 19:11:14
DataPoint Un-verified.	Jennifer Leyva (b) (4)	20 Nov 2020 19:10:24
User entered '15 Nov 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	20 Nov 2020 19:10:24
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:01:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:25
User entered empty.	Jennifer Leyva (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:26
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	11 Nov 2020 22:43:57
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		11 Nov 2020 22:43:57
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	11 Nov 2020 22:43:57
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	11 Nov 2020 22:41:43
User entered 'Unknown (UNK)'	Jennifer Leyva (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:29
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:30
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:32
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:34
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:39
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:49
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:51
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Leyva (b) (4)	11 Nov 2020 22:41:43
	(b) (4)	

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:52
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:55
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:56
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final outcome of the event, when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:52:34
Query 'PV Query: Please provide the final outcome of the event, when available.' answered with 'Will remain open/Not recovered until fully healed' (Site from Safety).	Jennifer Leyva (b) (4)	20 Nov 2020 19:11:31
User opened query 'PV Query: Please provide the final outcome of the event, when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:01:59
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:08:58
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Leyva (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:09:00
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:52:57
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:52:54
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:52:49
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Entered' (Site from Safety).	Jennifer Leyva (b) (4)	20 Nov 2020 19:11:43
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Entered' (Site from Safety).	Jennifer Leyva (b) (4)	20 Nov 2020 19:11:39
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Entered' (Site from Safety).	Jennifer Leyva (b) (4)	20 Nov 2020 19:11:35
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:01:51

v6.020 DTW (1102)

1515 of 2026

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:01:43
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:01:15
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:00:51
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:09:08
User entered 'Subject reported being shot during an invasion/break in at his home. Subject was shot twice, once in the Right shoulder and the second pierced both lungs causing collapse and is currently lodged in subject's spine. Currently hospitalized.'	Jennifer Leyva (b) (4)	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 22:41:43

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:39:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:47
User entered 'USA-US006-2020-mRNA-1273-P301000003'	(b) (4), (b) (6)	12 Nov 2020 16:29:42

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:28
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pneumothorax, LLT: Collapse of lung - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 00:33:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 00:33:38
Data point term sent to Coder	System	11 Nov 2020 22:43:04
User entered 'Bilateral Lung Collapse'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:36
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:39
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:41
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:43:52
DataPoint Un-verified.	Jennifer Leyva (b) (4)	20 Nov 2020 19:12:55
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 19:12:55
DataPoint Verified.	Jennifer Leyva (b) (4)	20 Nov 2020 19:12:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:42
	(b) (4)	
User entered '08 Nov 2020'	Jennifer Leyva (b) (4)	11 Nov 2020 22:42:27
	(b) (4)	

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:43:54
DataPoint Un-verified.	Jennifer Leyva (b) (4)	20 Nov 2020 19:06:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 19:06:30
DataPoint Verified.	Jennifer Leyva (b) (4)	12 Nov 2020 16:10:45
User entered 'Yes (Y)'	(b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:53:05
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Updated' (Site from Safety). DataPoint Un-verified.	Jennifer Leyva (b) (4)	20 Nov 2020 19:09:32
User entered '15 Nov 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	20 Nov 2020 19:06:30
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:03:16
User entered empty.	Jennifer Leyva (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:51
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:54
User entered 'Grade 4 (Grade 4)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:10:55
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:04
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:05
User entered '1'	Jennifer Leyva (b) (4)	11 Nov 2020 22:42:27
	(b) (4)	

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 09:03:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:07
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject is currently hospitalized. Discharge date not known.' (Site from System).	Jennifer Leyva (b) (4)	11 Nov 2020 22:43:16
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	11 Nov 2020 22:42:27
User entered 'I'	Jennifer Leyva (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:08
User entered '08 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:53:11
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:46:48
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Updated' (Site from Safety).	Jennifer Leyva (b) (4)	20 Nov 2020 19:09:39
DataPoint Un-verified.	Jennifer Leyva (b) (4)	20 Nov 2020 19:06:30
User entered '15 Nov 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	20 Nov 2020 19:06:30
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:03:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:10
User entered empty.	Jennifer Leyva (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:11
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	11 Nov 2020 22:42:51
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		11 Nov 2020 22:42:51
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	11 Nov 2020 22:42:51
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	11 Nov 2020 22:42:27
User entered 'Unknown (UNK)'	Jennifer Leyva (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:13
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:14
User entered '0'	Jennifer Leyva (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:16
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:18
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:19
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:21
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:22
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Leyva (b) (4)	11 Nov 2020 22:42:27
	(b) (4)	

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:28
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:30
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:32
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Outcome](#)

Audit	User	Time (GMT)
Query 'Per source page, event is still ongoing. Please clarify. Please also ensure both events in this SAE have their outcomes reviewed and updated as medical records are obtained. ' canceled (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:03:36
	(b) (4), (b) (6)	24 Nov 2020 19:03:35
User opened query 'Per source page, event is still ongoing. Please clarify. Please also ensure both events in this SAE have their outcomes reviewed and updated as medical records are obtained. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:48:14
Query 'PV Query: Please provide the final outcome of the event, when available.' answered with 'Updated' (Site from Safety).	Jennifer Leyva (b) (4)	20 Nov 2020 19:09:44
DataPoint Un-verified.	Jennifer Leyva (b) (4)	20 Nov 2020 19:06:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	20 Nov 2020 19:06:30
User opened query 'PV Query: Please provide the final outcome of the event, when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:04:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Leyva (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:35
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'CMs entered' (Site from Safety).	Jennifer Leyva (b) (4)	20 Nov 2020 19:10:05
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Entered' (Site from Safety).	Jennifer Leyva (b) (4)	20 Nov 2020 19:09:59
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:03:50
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:03:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:36
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Nov 2020 22:43:36
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	11 Nov 2020 22:43:36
User entered 'SUBJECT REPORTED BEING SHOT DURING AN INVASION/BREAK IN AT HIS HOME. SUBJECT WAS SHOT TWICE, ONCE IN THE RIGHT SHOULDER AND THE SECOND PIERCED BOTH LUNGS CAUSING COLLAPSE AND IS CURRENTLY LODGED IN SUBJECT'S SPINE. CURRENTLY HOSPITALIZED.' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	11 Nov 2020 22:43:36

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Nov 2020 22:42:27
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 22:42:27

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	21 Nov 2020 09:05:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Nov 2020 09:05:02
Data point term sent to Coder	System	20 Nov 2020 18:59:28
User entered 'Post-Traumatic Anxiety'	Jennifer Leyva (b) (4)	20 Nov 2020 18:59:13
	(b) (4)	

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 19:00:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 19:00:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	20 Nov 2020 19:00:31
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 18:59:13
User entered empty.	Jennifer Leyva (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '09 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[None](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'l'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Nov 2020 18:59:13

US3012263

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:43:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Nov 2020 19:00:31

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:03
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 09:05:03
Data point term sent to Coder	System	20 Nov 2020 19:04:32
User entered 'Rash, back and buttocks'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 19:04:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 19:04:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	20 Nov 2020 19:04:01
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 19:03:36
User entered empty.	Jennifer Leyva (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '15 Nov 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	20 Nov 2020 19:04:44
User entered '18 Nov 2020'	Jennifer Leyva (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[None](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Nov 2020 19:03:36

US3012263

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 08:43:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Nov 2020 19:04:01

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Fractures and dislocations NEC, PT: Traumatic fracture, LLT: Traumatic fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 12:25:10
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 12:25:10
Data point term sent to Coder	System	20 Nov 2020 19:15:46
User entered 'COMPOUND FRACTURE, T4 AND T3 RIBS, secondary to gunshot wound' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:21
User entered 'Compound Fracture, T4 and T3 ribs'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 19:15:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 19:15:21
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:21
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 19:15:03
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '09 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Is the adverse event serious is No, System but seriousness criteria is provided. Please correct.' (Site from System).	System	20 Nov 2020 19:23:25
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 19:15:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 19:15:21
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	20 Nov 2020 19:15:21
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	20 Nov 2020 19:15:21
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 19:15:03
User entered empty.	Jennifer Leyva (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	20 Nov 2020 19:23:25
User entered '1'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4)	20 Nov 2020 19:23:25
User entered '09 Nov 2020'	Jennifer Leyva (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4)	20 Nov 2020 19:23:25
User entered '15 Nov 2020'	Jennifer Leyva (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4)	20 Nov 2020 19:23:25
User entered 'No (N)'	Jennifer Leyva (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[None](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'l'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Nov 2020 19:15:21

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Nov 2020 19:15:03

US3012263

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 08:43:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Nov 2020 19:15:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:43:26

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:11:46
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 22:57:11

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: GLIBENCLAMIDE;METFORMIN HYDROCHLORIDE, PRODUCTSYNONYM: GLYBURIDE/METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 23:09:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 23:09:56
Data point term sent to Coder	System	02 Sep 2020 23:08:34
User entered 'glyburide/metformin'	Jennifer Leyva (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
User entered 'Diabetes, type II'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5/500'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 23:08:00

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:09:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:09:57
Data point term sent to Coder	System	02 Sep 2020 23:09:35
User entered 'lisinopril'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 23:09:18

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:10:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:10:58
Data point term sent to Coder	System	02 Sep 2020 23:10:37
User entered 'ibuprofen'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
User entered 'general myalgias'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '400'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 23:09:46

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 02:25:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 02:25:29
Data point term sent to Coder	System	29 Oct 2020 20:25:04
Data point term sent to Coder	System	29 Oct 2020 20:21:58
Coding entries removed.	Pamela Fidler (b) (4)	29 Oct 2020 20:21:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 23:12:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 23:12:54
Data point term sent to Coder	System	02 Sep 2020 23:11:40
User entered 'gabapentin'	Jennifer Leyva (b) (4)	02 Sep 2020 23:11:04
	(b) (4)	

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the location of DIABETIC NEUROPATHY as well as the type (sensory, motor). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 11:22:43
Query 'Per DM CLR: Please update the indication to reflect the location of DIABETIC NEUROPATHY as well as the type (sensory, motor). Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'Updated' (Site from DM).	Pamela Fidler (b) (4)	29 Oct 2020 20:24:22
User entered 'DIABETIC NEUROPATHY L FOOT Sensory' reason for change: Data Entry Error	Pamela Fidler (b) (4)	29 Oct 2020 20:24:17
User entered 'DIABETIC NEUROPATHY L Foot' reason for change: Data Entry Error	Pamela Fidler (b) (4)	29 Oct 2020 20:21:27
User opened query 'Per DM CLR: Please update the indication to reflect the location of DIABETIC NEUROPATHY as well as the type (sensory, motor). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:25:55
Query 'Per DM CLR: Please update the indication to reflect the location of DIABETIC NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:25:25
User opened query 'Per DM CLR: Please update the indication to reflect the location of DIABETIC NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:25:17
User entered 'diabetic neuropathy'	Jennifer Leyva (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '600'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '22 Jun 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 23:11:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:13:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:13:55
Data point term sent to Coder	System	29 Oct 2020 20:24:01
Data point term sent to Coder	System	29 Oct 2020 20:21:58
Coding entries removed.	Pamela Fidler (b) (4) (b) (4) (b) (4)	29 Oct 2020 20:21:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 09:54:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 09:54:38
Data point term sent to Coder	System	02 Sep 2020 23:11:38
User entered 'ibuprofen'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the location of DIABETIC NEUROPATHY as well as the type (sensory, motor). Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 11:22:56
Query 'Per DM CLR: Please update the indication to reflect the location of DIABETIC NEUROPATHY as well as the type (sensory, motor). Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'Updated' (Site from DM).	Pamela Fidler (b) (4)	29 Oct 2020 20:24:03
User entered 'DIABETIC NEUROPATHY L FOOT Sensory' reason for change: Data Entry Error	Pamela Fidler (b) (4)	29 Oct 2020 20:23:57
User entered 'DIABETIC NEUROPATHY L Foot' reason for change: Data Entry Error	Pamela Fidler (b) (4)	29 Oct 2020 20:21:49
User opened query 'Per DM CLR: Please update the indication to reflect the location of DIABETIC NEUROPATHY as well as the type (sensory, motor). Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:26:19
User entered 'diabetic neuropathy'	Jennifer Leyva (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '400'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered 'UN Feb 2019'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 23:11:28

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 20:20:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 20:20:51
Data point term sent to Coder	System	16 Sep 2020 20:19:34
User entered 'Tylenol'	Katherine Davis (b) (4)	16 Sep 2020 20:19:10
	(b) (4)	

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
User entered 'chills'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	16 Oct 2020 18:54:48
User entered '2'	Katherine Davis (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per CDM, per DM CLR re-query: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug as per the DM CLR query below on this page. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 11:23:14
Query 'Per CDM, per DM CLR re-query: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug as per the DM CLR query below on this page. Thank you. ' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4)	16 Oct 2020 18:54:55
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	16 Oct 2020 18:54:48
User opened query 'Per CDM, per DM CLR re-query: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug as per the DM CLR query below on this page. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:14:42
User entered 'tablet (TABLET)'	Katherine Davis (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
User entered '07 Sep 2020'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '07 Sep 2020'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM, per DM CLR re-query: Response is noted; however, please confirm in a query response that the AR of CHILLS did not meet the AE reporting criteria, else add an entry to the AE eCRF. Thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 04:54:57
Query 'Per CDM, per DM CLR re-query: Response is noted; however, please confirm in a query response that the AR of CHILLS did not meet the AE reporting criteria, else add an entry to the AE eCRF. Thank you. ' answered with 'Reported by subject in diary. Additional AE reporting not required' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	16 Oct 2020 18:55:10
User opened query 'Per CDM, per DM CLR re-query: Response is noted; however, please confirm in a query response that the AR of CHILLS did not meet the AE reporting criteria, else add an entry to the AE eCRF. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:12:24
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the CHILLS is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of CHILLS did not meet the AE reporting criteria. Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:12:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the CHILLS is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of CHILLS did not meet the AE reporting criteria. Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'Reported on Day 6 of Diary Dose 1' (Site from DM).	Jennifer Leyva (b) (4)	13 Oct 2020 14:50:44
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the CHILLS is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of CHILLS did not meet the AE reporting criteria. Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 10:19:39
	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 20:19:10

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 02:02:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 02:02:42
Data point term sent to Coder	System	16 Sep 2020 20:20:37
User entered 'Amoxicilin'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: The CM indication reflects a procedure was performed however, there are no Con Procs recorded. Please add a Con Proc as necessary and ensure there is a corresponding AE/Med Hx recorded for the underlying reason for the procedure. Please reconcile and update any applicable eCRFs. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:15:34
Query 'Per DM CLR: The CM indication reflects a procedure was performed however, there are no Con Procs recorded. Please add a Con Proc as necessary and ensure there is a corresponding AE/Med Hx recorded for the underlying reason for the procedure. Please reconcile and update any applicable eCRFs. ' answered with 'Con-Procedure added' (Site from DM).	Jennifer Leyva (b) (4)	13 Oct 2020 14:52:15
User opened query 'Per DM CLR: The CM indication reflects a procedure was performed however, there are no Con Procs recorded. Please add a Con Proc as necessary and ensure there is a corresponding AE/Med Hx recorded for the underlying reason for the procedure. Please reconcile and update any applicable eCRFs. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:21:14
User entered 'Molar extraction'	Katherine Davis (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '875'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)' reason for change: Data Entry Error	Pamela Fidler (b) (4) (b) (4)	11 Nov 2020 17:32:13
User entered 'other (OTHER)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

If frequency is Other, specify

Audit	User	Time (GMT)
User closed query 'Per CDM: Please review if the Frequency could be selected from one of the available options in the dropdown list provided (e.g. twice daily). Kindly update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 08:27:09
Query 'Per CDM: Please review if the Frequency could be selected from one of the available options in the dropdown list provided (e.g. twice daily). Kindly update as appropriate, else clarify.' answered with 'updated' (Site from DM).	Pamela Fidler (b) (4)	11 Nov 2020 17:32:19
User entered empty; reason for change Data Entry Error	Pamela Fidler (b) (4)	11 Nov 2020 17:32:13
User opened query 'Per CDM: Please review if the Frequency could be selected from one of the available options in the dropdown list provided (e.g. twice daily). Kindly update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:31:03
User entered 'Every 12 Hours'	Katherine Davis (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Nov 2020 17:32:13
User entered empty.	System	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 17:32:13
User entered empty.	System	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Nov 2020 17:32:13
User entered empty.	System	16 Sep 2020 20:20:24

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

[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: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 20:22:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 20:22:40
Data point term sent to Coder	System	16 Sep 2020 20:21:44
User entered 'Norco'	Katherine Davis (b) (4)	16 Sep 2020 20:21:05
	(b) (4)	

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: The CM indication reflects a procedure was performed however, there are no Con Procs recorded. Please add a Con Proc as necessary and ensure there is a corresponding AE/Med Hx recorded for the underlying reason for the procedure. Please reconcile and update any applicable eCRFs. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:15:45
Query 'Per DM CLR: The CM indication reflects a procedure was performed however, there are no Con Procs recorded. Please add a Con Proc as necessary and ensure there is a corresponding AE/Med Hx recorded for the underlying reason for the procedure. Please reconcile and update any applicable eCRFs. ' answered with 'Con-Procedure added' (Site from DM).	Jennifer Leyva (b) (4)	13 Oct 2020 14:52:23
User opened query 'Per DM CLR: The CM indication reflects a procedure was performed however, there are no Con Procs recorded. Please add a Con Proc as necessary and ensure there is a corresponding AE/Med Hx recorded for the underlying reason for the procedure. Please reconcile and update any applicable eCRFs. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:21:32
User entered 'molar extraction'	Katherine Davis (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10/325'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 20:21:05

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:12:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:47:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:47:38
Data point term sent to Coder	System	11 Nov 2020 22:46:10
User entered 'Robaxin'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:12:51
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:12:53
User entered 'pain, due to gunshot wound (AE #2)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:15
User closed query 'Per source, dose is 500mg. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 20:57:51
Query 'Per source, dose is 500mg. Please review and clarify. ' answered with 'updated' (Site from CRA).	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:19
User entered '500' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:12
User opened query 'Per source, dose is 500mg. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:50:19
User entered 'UNK'	Jennifer Leyva (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:20
User entered 'mg (mg)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:12
User entered 'Other (OTHER)'	Jennifer Leyva (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:23
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:12
User entered 'UNK'	Jennifer Leyva (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per source, frequency is TID. Please review and clarify. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:31
	(b) (4), (b) (6)	24 Nov 2020 21:02:28
Query 'Per source, frequency is TID. Please review and clarify. ' answered with 'updated' (Site from CRA).	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:21
User entered 'three times daily (TID)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:12
User opened query 'Per source, frequency is TID. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:50:42
User entered 'unknown (UNKNOWN)'	Jennifer Leyva (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:35
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:38
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:03:00
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:03:08
User closed query 'Per source, start date was updated to 09Nov20. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 21:03:06
DataPoint Un-verified.	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:32
User entered '09 Nov 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:32
Query 'Per source, start date was updated to 09Nov20. Please review and clarify. ' answered with 'updated' (Site from CRA).	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:24
User opened query 'Per source, start date was updated to 09Nov20. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:51:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:13:04
User entered '08 Nov 2020'	Jennifer Leyva (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:03:11
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per source, end date is 15Nov20. Please review and clarify. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:03:47
	(b) (4), (b) (6)	24 Nov 2020 21:03:45
Query 'Per source, end date is 15Nov20. Please review and clarify. ' answered with 'updated' (Site from CRA). DataPoint Un-verified.	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:26
	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:12
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:12
User opened query 'Per source, end date is 15Nov20. Please review and clarify. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:51:22
	(b) (4), (b) (6)	12 Nov 2020 16:13:38
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:03:50
User entered '15 Nov 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:12
User entered empty.	Jennifer Leyva (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:03:52
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Nov 2020 16:42:12
User entered empty.	System	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 16:42:12
User entered empty.	System	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Nov 2020 16:42:12
User entered empty.	System	11 Nov 2020 22:45:35

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:13:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:47:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:47:39
Data point term sent to Coder	System	11 Nov 2020 22:46:19
User entered 'Tylenol'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:13:25
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:13:24
User entered 'pain, due to gunshot wound (AE #2)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:10
User entered '1000' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:59
User entered 'UNK'	Jennifer Leyva (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:12
User entered 'mg (mg)' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:59
User entered 'Other (OTHER)'	Jennifer Leyva (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:15
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:59
User entered 'UNK'	Jennifer Leyva (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:17
User entered 'as needed (PRN)' reason for change:	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:59
Data Entry Error	(b) (4)	
User entered 'unknown (UNKNOWN)'	Jennifer Leyva (b) (4)	11 Nov 2020 22:46:03
	(b) (4)	

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:19
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:21
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4)	11 Nov 2020 22:46:03
	(b) (4)	

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:23
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:26
DataPoint Un-verified.	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:59
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4)	23 Nov 2020 16:42:59
DataPoint Verified.	Jennifer Leyva (b) (4)	23 Nov 2020 16:42:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:13:31
	(b) (4)	
User entered '08 Nov 2020'	Jennifer Leyva (b) (4)	11 Nov 2020 22:46:03
	(b) (4)	

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:28
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:13:33
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:31
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:04:32
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:46:03

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:06:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:05
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 09:05:05
Data point term sent to Coder	System	20 Nov 2020 18:58:26
User entered 'Tramadol'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:06:54
User entered 'No (N)'	Jennifer Leyva (b) (4)	20 Nov 2020 18:58:20
	(b) (4)	

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:06:56
User entered 'Pain, due to gunshot wound (AE #2)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:06:59
User entered '50'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:03
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:05
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:07
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:09
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:11
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:14
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:16
User entered '15 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:17
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:20
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:23
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:25
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 18:58:20

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:02:00
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 09:02:00
Data point term sent to Coder	System	20 Nov 2020 19:02:29
User entered 'Alprazolam'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:54
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:57
User entered 'Anxiety (AE #4)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:08:17
User entered '2'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:08:19
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:08:21
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:10
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:12
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:17
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:22
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:24
User entered '18 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:26
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:28
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:31
User entered empty.	Jennifer Leyva (b) (4)	20 Nov 2020 19:01:45
	(b) (4)	

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:33
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:01:45

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:49
Data point term sent to Coder	System	20 Nov 2020 19:02:30
User entered 'Methocarbamol'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:42
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:44
User entered 'pain, due to gunshot wound (AE #2)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:47
User entered '500'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:49
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:51
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:53
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:56
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:09:58
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:01
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:04
User entered '18 Nov 2020'	Jennifer Leyva (b) (4)	20 Nov 2020 19:02:15
	(b) (4)	

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:07
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:10
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:11
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:14
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:02:15

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:20
User coded data point as ATC: ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS, ATC: ANTIPROTOZOALS, ATC: AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES, ATC: NITROIMIDAZOLE DERIVATIVES, PRODUCT: CLOTRIMAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:02:20
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 09:02:20
Data point term sent to Coder	System	20 Nov 2020 19:04:32
User entered 'Clotrimazole 1%'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:22
User entered 'No (N)'	Jennifer Leyva (b) (4)	20 Nov 2020 19:04:27
	(b) (4)	

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:24
User entered 'Rash (AE #5)'	Jennifer Leyva (b) (4)	20 Nov 2020 19:04:27
	(b) (4)	

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:26
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:29
User entered 'Other (OTHER)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:31
User entered 'application'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:33
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:36
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:38
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:41
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:43
User entered '15 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:46
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:48
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:50
User entered empty.	Jennifer Leyva (b) (4)	20 Nov 2020 19:04:27
	(b) (4)	

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:10:52
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:04:27

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:04:27

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:04:27

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 19:04:27

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:24:47
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 21:11:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:11:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:34
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 09:04:34
Data point term sent to Coder	System	20 Nov 2020 19:08:35
User entered 'Glipizide'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:24:48
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 21:11:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:11:10
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:24:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 21:11:19
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:11:13
User entered 'DIABETES, TYPE II (while hospitalized)'	Jennifer Leyva (b) (4)	20 Nov 2020 19:08:19

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:24:52
User entered '5'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:24:56
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:24:57
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:24:59
User entered 'once daily (QD)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:01
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:02
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:04
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:06
User entered '09 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:07
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:08
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:10
User entered '15 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:11
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:08:19

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 19:08:19

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 19:08:19

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 19:08:19

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:43
Data point term sent to Coder	System	20 Nov 2020 19:09:36
User entered 'Insulin'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:20
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:21
User entered 'DIABETES, TYPE II (while hospitalized)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:23
User entered 'NA'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:24
User entered 'Other (OTHER)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:26
User entered 'Sliding Scale'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:27
User entered 'once daily (QD)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:29
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:31
User entered 'Intramuscular (INTRAMUSCULAR)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:32
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:34
User entered '09 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:35
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:37
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:38
User entered '15 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:25:39
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 08:43:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 19:09:04

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:43:26

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:13:42
User entered 'Yes (Y)' reason for change: New Information	Jennifer Leyva (b) (4)	13 Oct 2020 14:51:21
User entered 'No (N)'	Jennifer Leyva (b) (4)	02 Sep 2020 22:57:17

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:43:26

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 14:52:00

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:43:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'molar extraction'	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 14:52:00

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:27:29
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' answered with 'AE #1 = Loose molar. This Con-Proc corresponds to AE #1' (Site from DM).	Jennifer Leyva (b) (4)	02 Nov 2020 18:38:23
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 02:04:48
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4)	13 Oct 2020 14:52:00

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:43:26

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 14:52:00

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 08:43:26

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:06
DataPoint Un-verified.	Jennifer Leyva (b) (4)	20 Nov 2020 19:12:23
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 19:12:23
DataPoint Verified.	Jennifer Leyva (b) (4)	12 Nov 2020 16:13:52
User entered '08 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 22:46:32
	Jennifer Leyva (b) (4)	
	(b) (4)	

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 08:43:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:08
DataPoint Un-verified.	Jennifer Leyva (b) (4)	20 Nov 2020 19:12:23
User entered 'Bilateral Chest Tube Placement'	(b) (4)	
reason for change: Data Entry Error	Jennifer Leyva (b) (4)	20 Nov 2020 19:12:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 16:13:53
User entered 'Oxygen Treatment'	Jennifer Leyva (b) (4)	11 Nov 2020 22:46:32
	(b) (4)	

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:13:55
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4)	11 Nov 2020 22:46:32
	(b) (4)	

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 08:43:26

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:13:57
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Nov 2020 22:46:32

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 08:43:26

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:28
User entered '09 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:13:26

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 08:43:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:30
User entered 'CT Scan - Chest'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:13:26

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:31
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:13:26

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 08:43:26

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:33
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:13:26

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 08:43:26

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:36
User entered '09 Nov 2020'	Jennifer Leyva (b) (4)	20 Nov 2020 19:30:02
	(b) (4)	

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 08:43:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:38
User entered 'CT Scan - Abdomen and Pelvis'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:30:02

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:42
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4)	20 Nov 2020 19:30:02
	(b) (4)	

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 08:43:26

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:44
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:30:02

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 08:43:26

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:49
User entered '11 Nov 2020'	Jennifer Leyva (b) (4)	20 Nov 2020 19:30:16
	(b) (4)	

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 08:43:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:51
User entered 'Chest XRAY'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:30:16

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:52
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:30:16

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 08:43:26

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:54
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:30:16

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 08:43:26

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:12:57
User entered '12 Nov 2020'	Jennifer Leyva (b) (4)	20 Nov 2020 19:30:27
	(b) (4)	

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 08:43:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:13:00
User entered 'Chest XRAY'	Jennifer Leyva (b) (4)	20 Nov 2020 19:30:27
	(b) (4)	

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 08:43:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:13:02
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4)	20 Nov 2020 19:30:27
	(b) (4)	

US3012263

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 08:43:26

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:13:03
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 19:30:27

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'USA-US006-2020-MRNA-1273-P301000003'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Laurence'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Chu'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '3100 Red River Street'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Austin'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'TX'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '78705'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:11:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
User entered 'US'	System	12 Nov 2020 16:30:08

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Nov 2020 20:11:43
User entered '1'	System	12 Nov 2020 16:30:08

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'USA-US006-2020-MRNA-1273-P301000003'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Laurence'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Chu'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '3100 Red River Street'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Austin'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'TX'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '78705'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:11:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
User entered 'US'	System	12 Nov 2020 16:30:08

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Nov 2020 20:11:43
User entered '1'	System	12 Nov 2020 16:30:08

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:43:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
User entered '12/Nov/2020 11:30'	System	12 Nov 2020 16:30:08

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:43:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:11:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 16:30:08

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'USA-US006-2020-MRNA-1273-P301000003'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Yes (Y)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'No (N)'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Laurence'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Chu'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '3100 Red River Street'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'Austin'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered 'TX'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:29:59
User entered '78705'	System	12 Nov 2020 16:28:37

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:11:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:42:13
User entered 'US'	System	12 Nov 2020 16:30:08

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Nov 2020 20:11:43
User entered '1'	System	12 Nov 2020 16:30:08

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:43:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:51:05
User entered '23/Nov/2020 20:11'	System	23 Nov 2020 20:11:43

US3012263

Folder: SAE USA-US006-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:43:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:51:05
User entered 'I'	(b) (4), (b) (6)	23 Nov 2020 20:11:43