

US3252261 (Prod: Centex Studies Inc)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:51:44

All time stamps listed in this document are displayed in GMT

US3252261

Form: Participant Creation

Generated On: 26 Nov 2020 10:51:44

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:44

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	75
Age Units	YEARS
Age (Derived)	75
Sex	Female <input checked="" type="radio"/> Male <input 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

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:44

Date of Informed Consent (<i>dd MMM yyyy</i>)	20 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:51:44

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:51:44

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:44

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

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:44

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

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:44

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:44

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

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:44

Condition	HYPERLIPIDEMIA
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)	

US3252261

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:44

Condition	SEASONAL ALLERGIES (POLLEN, DUST)
Start date (dd MMM yyyy)	UN UNK 1960
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 1960
Start Year (derived)	1960
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:44

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	UN JAN 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JAN 1980
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	JAN 1980
Stop Year (derived)	1980

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:44

Condition	CERVICAL HYSTERECTOMY
Start date (dd MMM yyyy)	UN JAN 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JAN 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:44

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 1974
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1974
Start Year (derived)	1974
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	08:12 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 08:12
Height (<i>xxx.x</i>)	61 in
Weight (<i>xxx.x</i>)	245 lb
BMI (<i>xxx.x</i>)	46.38914 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:44

Date of assessment (<i>dd MMM yyyy</i>)	20 AUG 2020
Is the participant of childbearing potential?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If No, what is the reason?	Surgically sterile <input checked="" type="radio"/>
	Post-menopausal <input type="radio"/>
	Partner medically sterile <input type="radio"/>
	Not reached age of Menarche <input type="radio"/>
	Other <input type="radio"/>
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>)	UN JAN 1980
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

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)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:44

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 187206

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:44

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

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)	20 AUG 2020
Time of assessment (00:00-23:59)	08:12 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 08:12
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

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)	20 AUG 2020
Time of assessment (00:00-23:59)	10:17 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 10:17
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)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:44

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 20 AUG 2020

What was the treatment time? (00:00-23:59) 09:40 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 09:40

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	20 AUG 2020
Collection time (<i>00:00-23:59</i>)	09:02 (24 HR)
Collection date and time (derived)	20 AUG 2020 09:02

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:51:44

Collection date (<i>dd MMM yyyy</i>)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:44	20 AUG 2020 08:44
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 10:25

PC Open Date & Time

20 AUG 2020 10:00

PC Close Date & Time

20 AUG 2020 12:30

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	20 AUG 2020 14:47
PC Open Date & Time	20 AUG 2020 13:25
PC Close Date & Time	21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 12:03

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 12:14

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 13:36

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:44

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

98.0 °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

24 AUG 2020 12:05

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 12:00

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 12:02

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 10:25

PC Open Date & Time

20 AUG 2020 10:00

PC Close Date & Time

20 AUG 2020 12:30

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

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

20 AUG 2020 14:48

PC Open Date & Time

20 AUG 2020 13:25

PC Close Date & Time

21 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

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

21 AUG 2020 12:03

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

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

22 AUG 2020 12:15

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

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

23 AUG 2020 13:38

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:44

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

24 AUG 2020 12:06

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:44

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

25 AUG 2020 12:01

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:44

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

26 AUG 2020 12:03

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 10:26
PC Open Date & Time	20 AUG 2020 10:00
PC Close Date & Time	20 AUG 2020 12:30

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 14:49
PC Open Date & Time	20 AUG 2020 13:25
PC Close Date & Time	21 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

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 ☒

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 12:04
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

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 ☒

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 12:16
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

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 ☒

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 13:39
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

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 ☒

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 12:07
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

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 ☒

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 12:01
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

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 ☒

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 12:03
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3252261

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

Was Contact Attempted?

Yes ☒

No ☐

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

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252261

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

Was Contact Attempted?

Yes ☒

No ☐

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

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252261

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

Was Contact Attempted?

Yes ☒

No ☐

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

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252261

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

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)	16 SEP 2020
Time of assessment (00:00-23:59)	08:18 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 08:18
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

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)	16 SEP 2020
Time of assessment (00:00-23:59)	10:12 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 10:12
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3252261

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:44

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.

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

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)	16 SEP 2020
What was the treatment time? (00:00-23:59)	09:42 (24 HR)
Treatment Date and Time (derived)	16 SEP 2020 09:42
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

US3252261

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	16 SEP 2020
Collection time (<i>00:00-23:59</i>)	08:59 (24 HR)
Collection date and time (derived)	16 SEP 2020 08:59

US3252261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:51:44

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:52	16 SEP 2020 08:52
Nasopharyngeal Swab 2	No		

US3252261

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

16 SEP 2020 10:21

PC Open Date & Time

16 SEP 2020 10:02

PC Close Date & Time

16 SEP 2020 12:32

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.2 °F

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

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

PC Time Stamp	16 SEP 2020 13:44
PC Open Date & Time	16 SEP 2020 13:27
PC Close Date & Time	17 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 19:25

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 12:52

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 12:09

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

20 SEP 2020 13:19

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 13:35

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:44

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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 13:13

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 10:22

PC Open Date & Time

16 SEP 2020 10:02

PC Close Date & Time

16 SEP 2020 12:32

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

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

16 SEP 2020 13:45

PC Open Date & Time

16 SEP 2020 13:27

PC Close Date & Time

17 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

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 ☐

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

100

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)**

1

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

17 SEP 2020 19:28

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

1

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)**

1

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

18 SEP 2020 12:53

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

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 ☐

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

1

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)**

1

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

19 SEP 2020 12:12

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 13:19

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 13:35

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 13:14

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 10:22
PC Open Date & Time	16 SEP 2020 10:02
PC Close Date & Time	16 SEP 2020 12:32

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 13:45
PC Open Date & Time	16 SEP 2020 13:27
PC Close Date & Time	17 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

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 ☒

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 19:29
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

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 ☒

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:54
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

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 ☒

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 12:13
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

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 ☒

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 13:20
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

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 ☒

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 13:36
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

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 ☒

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 13:14
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3252261

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

Was Contact Attempted?

Yes ☒

No ☐

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

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252261

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

Was Contact Attempted?

Yes ☒

No ☐

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

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252261

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	07:31 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 07:31
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252261

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:44

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.

US3252261

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	13 OCT 2020
Collection time (<i>00:00-23:59</i>)	07:49 (24 HR)
Collection date and time (derived)	13 OCT 2020 07:49

US3252261

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 10:04:09

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 20:56:38

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 NOV 2020 08:50:52

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 09:32:53

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Open Date & Time](#)

17 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2020 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2020 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Open Date & Time](#)

07 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2020 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 96

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 15:04:00

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Open Date & Time](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

Patient Cloud Open Date & Time	05 DEC 2020 00:01
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Patient Cloud Close Date & Time	09 DEC 2020 23:59
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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Open Date & Time](#)

09 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

20 JAN 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 173

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

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

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

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

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

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

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

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Open Date & Time](#)

20 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Open Date & Time](#)

06 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Open Date & Time](#)

10 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 <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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2021 00:01
Patient Cloud Close Date & Time	13 OCT 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

Patient Cloud Open Date & Time	23 OCT 2021 00:01
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Patient Cloud Close Date & Time	27 OCT 2021 23:59
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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 <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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 MAR 2022 00:01
Patient Cloud Close Date & Time	30 MAR 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 <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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2022 00:01
Patient Cloud Close Date & Time	12 OCT 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

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

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

US3252261

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

Was Contact Attempted?

Yes ☒

No ☐

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

11 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252261

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3252261

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:51:44

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"/>

US3252261

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:51:44

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3252261

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:51:44

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

AEID	USA-US108-2020-MRNA-1273-P30 1000017
Adverse event	HEART FAILURE
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)	1 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)	3 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	1 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	3 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)	342 of 1892

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT ADMITTED BECAUSE OF SHORTNESS OF BREATH, SHE STAYED IN THE HOSPITAL FOR 3 DAYS AND GOT RELEASED. WE WILL REQUEST MEDICAL RECORDS.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

v6.020 DTW (1102)

343 of 1892

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:51:44

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

Yes ☒

No ☐

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

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

Name of Medication	METROPOLOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	50
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"/>

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	9 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2005
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

Name of Medication	LOSARTAN/HYDROCHLOROTHIAZIDE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	100/25
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"/>

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)	9 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	9 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPOTHYROIDISM
Dose per administration	112
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

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 1995
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2013
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2005
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

Name of Medication	OTC VITAMIN D
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	DIETARY SUPPLEMENT
Dose per administration	5000
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input checked="" 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

Name of Medication	OTC VITAMIN B12
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	DIETARY SUPPLEMENT
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input checked="" type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

Name of Medication	OTC MULTIVITAMIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>

Indication	DIETARY SUPPLEMENT
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input checked="" type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>

If dose unit is Other, specify

Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
-----------	--

If frequency is Other, specify

Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>
-------------------------	---

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

Name of Medication	ADVAIR
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ASTHMA
Dose per administration	230/21
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<input type="text"/>	
<hr/>		
Interval Dosage Unit Number (derived)	<input type="text"/>	
<hr/>		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

Name of Medication	FUROSEMIDE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HEART FAILURE
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"/>

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

Name of Medication	CARVEDILOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HEART FAILURE
Dose per administration	12
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"/>

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:51:44

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3252261

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:51:44

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

US3252261

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:51:44

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 ☐

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

SAEID	USA-US108-2020-MRNA-1273-P301000017
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:51:44

SAEID	USA-US108-2020-MRNA-1273-P301000017
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	12/NOV/2020 19:39
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

US3252261 (Prod: Centex Studies Inc)

US3252261

Form: Participant Creation

Generated On: 26 Nov 2020 10:51:44

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3252261'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	20 Aug 2020 13:19:44

US3252261

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:34:45

US3252261

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	20 Aug 2020 13:19:45

US3252261

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:34:45

US3252261

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	21 Aug 2020 14:34:45

US3252261

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:44

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1945'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 13:19:45

US3252261

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:44

[Age](#)

Audit	User	Time (GMT)
User entered '75'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:35:04

US3252261

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:44

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	21 Aug 2020 14:35:04

US3252261

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:44

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '75'	System	20 Aug 2020 14:12:47

US3252261

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:44

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:35:04

US3252261

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:44

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:35:04

US3252261

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:44

White

Audit	User	Time (GMT)
User entered 'I'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:35:04

US3252261

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:44

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:35:04

US3252261

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:44

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:35:04

US3252261

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:44

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:35:04

US3252261

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:44

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:35:04

US3252261

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:44

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:35:04

US3252261

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:44

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:35:04

US3252261

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:44

Unknown

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:35:04

US3252261

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:44

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:35:04

US3252261

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:44

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Uche Ehiemua (b) (4) (b) (4)	20 Aug 2020 14:12:47

US3252261

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	20 Aug 2020 14:12:47

US3252261

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '2020'	System	20 Aug 2020 14:12:47

US3252261

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:44

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Uche Ehiemua (b) (4) (b) (4)	20 Aug 2020 14:12:47

US3252261

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Uche Ehiemua (b) (4) (b) (4)	20 Aug 2020 14:12:47

US3252261

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:44

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	20 Aug 2020 14:12:47

US3252261

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:44

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	20 Aug 2020 14:12:47

US3252261

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:44

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Uche Ehiemua (b) (4) (b) (4)	20 Aug 2020 14:12:47

US3252261

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:44

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	20 Aug 2020 13:19:45

US3252261

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:44

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Aug 2020 14:13:03

US3252261

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:51:44

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Uche Ehiemua (b) (4) (b) (4)	20 Aug 2020 14:13:03

US3252261

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:51:44

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:35:44

US3252261

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:44

[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)	21 Aug 2020 14:37:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:37:25
Data point term sent to Coder	System	21 Aug 2020 14:36:48
User entered 'Hypertension'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:03
	(b) (4)	

US3252261

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:03

US3252261

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:03

US3252261

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:03

US3252261

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:03

US3252261

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:03

US3252261

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	21 Aug 2020 14:36:03

US3252261

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '2005'	System	21 Aug 2020 14:36:03

US3252261

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 14:36:03

US3252261

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 14:36:03

US3252261

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:44

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:37:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:37:25
Data point term sent to Coder	System	21 Aug 2020 14:36:49
User entered 'Hypothyroidism'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:19
	(b) (4)	

US3252261

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:19

US3252261

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:19

US3252261

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:19

US3252261

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:19

US3252261

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:19

US3252261

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	21 Aug 2020 14:36:19

US3252261

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '2005'	System	21 Aug 2020 14:36:19

US3252261

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 14:36:19

US3252261

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 14:36:19

US3252261

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:37:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:37:25
Data point term sent to Coder	System	21 Aug 2020 14:36:49
User entered 'Asthma'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:35

US3252261

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 1995'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:35

US3252261

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:35

US3252261

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:35

US3252261

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:35

US3252261

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:35

US3252261

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	21 Aug 2020 14:36:35

US3252261

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '1995'	System	21 Aug 2020 14:36:35

US3252261

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 14:36:35

US3252261

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 14:36:35

US3252261

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:44

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:39:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:39:18
Data point term sent to Coder	System	21 Aug 2020 14:37:50
User entered 'Gastroesophageal reflux disease'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:52

US3252261

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2020'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:52

US3252261

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:52

US3252261

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:52

US3252261

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:52

US3252261

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:36:52

US3252261

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	21 Aug 2020 14:36:52

US3252261

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '2020'	System	21 Aug 2020 14:36:52

US3252261

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 14:36:52

US3252261

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 14:36:52

US3252261

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:39:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:39:17
Data point term sent to Coder	System	21 Aug 2020 14:37:50
User entered 'Hyperlipidemia'	Shannon Moyer (b) (4)	21 Aug 2020 14:37:09
	(b) (4)	

US3252261

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:37:09

US3252261

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:37:09

US3252261

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:37:09

US3252261

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:37:09

US3252261

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:37:09

US3252261

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	21 Aug 2020 14:37:09

US3252261

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '2005'	System	21 Aug 2020 14:37:09

US3252261

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 14:37:09

US3252261

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 14:37:09

US3252261

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:44

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please verify if this refers to Allergy to pollen,dust. If so, update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 11:29:34
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 16:21:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 16:21:14
Data point term sent to Coder	System	30 Sep 2020 14:42:31
Query 'Per DM CLR: Please verify if this refers to Allergy to pollen,dust. If so, update the eCRF as appropriate.' answered with 'Condition updated' (Site from DM).	Uche Ehiemua (b) (4) (b) (4)	30 Sep 2020 14:42:12
User entered 'SEASONAL ALLERGIES (POLLEN, DUST)' reason for change: Data Entry Error	Uche Ehiemua (b) (4) (b) (4)	30 Sep 2020 14:42:02
User opened query 'Per DM CLR: Please verify if this refers to Allergy to pollen,dust. If so, update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:29:11
Data point term sent to Coder	System	21 Aug 2020 14:37:50
User entered 'Pollen, dust (Runny nose, sneezing, congestion, watery eyes)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:37:47

US3252261

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 1960'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:37:47

US3252261

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:37:47

US3252261

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:37:47

US3252261

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:37:47

US3252261

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:37:47

US3252261

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Jan 1960'	System	21 Aug 2020 14:37:47

US3252261

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '1960'	System	21 Aug 2020 14:37:47

US3252261

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 14:37:47

US3252261

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 14:37:47

US3252261

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 17:28:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 17:28:51
Data point term sent to Coder	System	15 Sep 2020 17:27:41
Coding entries removed.	Joanna Gurrola (b) (4)	15 Sep 2020 17:27:33
User entered 'BILATERAL TUBAL LIGATION' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	15 Sep 2020 17:27:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:40:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:40:21
Data point term sent to Coder	System	21 Aug 2020 14:38:52
User entered 'Tubal ligation'	Shannon Moyer (b) (4)	21 Aug 2020 14:38:11

US3252261

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN Jan 1980'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:38:11

US3252261

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:38:11

US3252261

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:38:11

US3252261

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN Jan 1980'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:38:11

US3252261

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:38:11

US3252261

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	21 Aug 2020 14:38:11

US3252261

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '1980'	System	21 Aug 2020 14:38:11

US3252261

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	21 Aug 2020 14:38:11

US3252261

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '1980'	System	21 Aug 2020 14:38:11

US3252261

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:44

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:00:42
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'Associated condition added to MH' (Site from DM).	Uche Ehiemua (b) (4)	30 Sep 2020 14:47:38
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:30:03
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 22:54:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 22:54:26
Data point term sent to Coder	System	21 Aug 2020 14:38:53
User entered 'Cervical hysterectomy'	Shannon Moyer (b) (4)	21 Aug 2020 14:38:36

US3252261

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN Jan 1985'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:38:36

US3252261

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:38:36

US3252261

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:38:36

US3252261

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN Jan 1985'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:38:36

US3252261

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:38:36

US3252261

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	21 Aug 2020 14:38:36

US3252261

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '1985'	System	21 Aug 2020 14:38:36

US3252261

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	21 Aug 2020 14:38:36

US3252261

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '1985'	System	21 Aug 2020 14:38:36

US3252261

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:48:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:48:53
Data point term sent to Coder	System	30 Sep 2020 14:47:52
User entered 'Menorrhagia'	Uche Ehiemua (b) (4)	30 Sep 2020 14:47:00

US3252261

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 1974'	Uche Ehiemua (b) (4) (b) (4)	30 Sep 2020 14:47:00

US3252261

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	30 Sep 2020 14:47:00

US3252261

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Uche Ehiemua (b) (4) (b) (4)	30 Sep 2020 14:47:00

US3252261

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 1985'	Uche Ehiemua (b) (4) (b) (4)	30 Sep 2020 14:47:00

US3252261

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	30 Sep 2020 14:47:00

US3252261

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Jan 1974'	System	30 Sep 2020 14:47:00

US3252261

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '1974'	System	30 Sep 2020 14:47:00

US3252261

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	30 Sep 2020 14:47:00

US3252261

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '1985'	System	30 Sep 2020 14:47:00

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:39:40

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:39:40

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '08:12'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:39:40

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 08:12'	System	21 Aug 2020 14:39:40

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

Height (xxx.x)

Audit	User	Time (GMT)
User entered '61' in	Shannon Moyer (b) (4)	21 Aug 2020 14:39:40
DataPoint set to visible.	(b) (4) System	20 Aug 2020 14:13:03

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '245' lb	Shannon Moyer (b) (4)	21 Aug 2020 14:39:40
DataPoint set to visible.	(b) (4) System	20 Aug 2020 14:13:03

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
Amendment Manager: User entered '46.38914'	System	17 Sep 2020 00:15:34
User entered '46.4'	System	21 Aug 2020 14:39:40
DataPoint set to visible.	System	20 Aug 2020 14:13:03

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	21 Aug 2020 14:39:40
DataPoint set to visible.	System	20 Aug 2020 14:13:03

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:39:40

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:39:40

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:39:40

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:39:40

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Aug 2020 14:39:40

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:39:40

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Aug 2020 14:39:40

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:39:40

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 14:39:40

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:39:40

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 14:39:40

US3252261

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:44

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:40:20

US3252261

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	23 Sep 2020 18:56:21
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		16 Sep 2020 14:42:25
User entered '20 Aug 2020'	Shannon Moyer (b) (4)	21 Aug 2020 14:40:20
	(b) (4)	

US3252261

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:41:12

US3252261

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:44

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:41:12

US3252261

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:44

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 18:34:24
Query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification. ' answered with 'UPDATED' (Site from DM).	Joanna Gurrola (b) (4) (b) (4)	15 Sep 2020 17:26:55
User opened query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 10:04:28
User closed query 'Partner medically sterile or Other System has not been entered, however specify is provided. Please correct.' (Site from System).		21 Aug 2020 15:07:46
User opened query 'Partner medically sterile or Other System has not been entered, however specify is provided. Please correct.' (Site from System).		21 Aug 2020 14:41:12
User entered 'Surgically sterile (SURGICALLY STERILE)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:41:12

US3252261

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:44

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 15:07:46
User entered 'tubal ligation'	Shannon Moyer (b) (4)	21 Aug 2020 14:41:12

US3252261

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN Jan 1980'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:41:12

US3252261

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:44

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:41:12

US3252261

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:41:12

US3252261

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:44

Date of last menstruation unknown

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:41:12

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

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)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

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)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

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)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

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)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

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)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

[Specify](#)

Audit	User	Time (GMT)
User entered 'Retired'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

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'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

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'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '1'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:44

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:11

US3252261

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:31

US3252261

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:31

US3252261

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:42:31

US3252261

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	21 Aug 2020 14:42:31

US3252261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	20 Aug 2020 13:39:36

US3252261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:44

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:47:45
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:47:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 13:39:36
User entered '187206' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 13:39:36

US3252261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	20 Aug 2020 13:39:36

US3252261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Uche Ehiemua (b) (4) (b) (4)	20 Aug 2020 14:13:46

US3252261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Uche Ehiemua (b) (4) (b) (4)	20 Aug 2020 14:13:46

US3252261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Uche Ehiemua (b) (4) (b) (4)	20 Aug 2020 14:13:46

US3252261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:44

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Uche Ehiemua (b) (4) (b) (4)	20 Aug 2020 14:13:46

US3252261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:44

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Uche Ehiemua (b) (4) (b) (4)	20 Aug 2020 14:13:46

US3252261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4)	01 Oct 2020 06:39:46
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:37
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:41:08

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:44

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	02 Sep 2020 05:13:11
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:44

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	02 Sep 2020 05:13:11
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:44

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	02 Sep 2020 05:13:11
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:44

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	02 Sep 2020 05:13:11
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '08:12'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 08:12'	System	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.8' F	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

Pulse (xxx)

Audit	User	Time (GMT)
User entered '78'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '15'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '116'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:44

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	02 Sep 2020 05:13:11
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:44

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	02 Sep 2020 05:13:11
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '10:17'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 10:17'	System	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '75'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '15'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '138'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '84'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	28 Aug 2020 16:22:06
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:44:35

US3252261

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	28 Aug 2020 16:22:06
User entered '20 Aug 2020'	Shannon Moyer (b) (4)	21 Aug 2020 14:44:35

US3252261

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 15:08:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 15:08:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:08:44
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 15:03:52
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	20 Aug 2020 15:03:52

US3252261

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	20 Aug 2020 15:03:52

US3252261

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	20 Aug 2020 15:03:52

US3252261

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 15:08:44
User entered empty.	System	20 Aug 2020 15:03:52

US3252261

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	20 Aug 2020 15:03:52

US3252261

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '09:40'	Joanna Gurrola (b) (4) (b) (4)	20 Aug 2020 15:03:52

US3252261

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 09:40'	System	20 Aug 2020 15:03:52

US3252261

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 15:08:44
User entered empty.	(b) (4)	
	Joanna Gurrola (b) (4)	20 Aug 2020 15:03:52
	(b) (4)	

US3252261

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	21 Aug 2020 15:08:44
User entered empty.	System	20 Aug 2020 15:03:52

US3252261

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 15:08:44
User entered empty.	System	20 Aug 2020 15:03:52

US3252261

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:44:57

US3252261

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:44:57

US3252261

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:02'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:44:57

US3252261

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 09:02'	System	21 Aug 2020 14:44:57

US3252261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:51:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:45:22

US3252261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:45:22

US3252261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:45:22

US3252261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '08:44'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:45:22

US3252261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 08:44'	System	21 Aug 2020 14:45:22

US3252261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:45:22

US3252261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:45:22

US3252261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:45:22

US3252261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 14:45:22

US3252261

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:45:30

US3252261

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:45:30

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:25:38', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '426ad3a7-9ad0-47cb-903f-2cf40c9329a7'	System	20 Aug 2020 15:27:57
User entered 'Yes (Y)'	System	20 Aug 2020 15:27:57

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:25:42', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '426ad3a7-9ad0-47cb-903f-2cf40c9329a7'	System	20 Aug 2020 15:27:57
User entered '98.2'	System	20 Aug 2020 15:27:57

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:25:44', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '426ad3a7-9ad0-47cb-903f-2cf40c9329a7'	System	20 Aug 2020 15:27:57
User entered 'No (N)'	System	20 Aug 2020 15:27:57

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:25:48', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '426ad3a7-9ad0-47cb-903f-2cf40c9329a7'	System	20 Aug 2020 15:27:57
User entered '20 Aug 2020 10:25'	System	20 Aug 2020 15:27:57

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 10:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:30'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:47:05', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '3d66b0d0-7896-43ee-8773-ad385ba36325'	System	20 Aug 2020 19:49:41
User entered 'Yes (Y)'	System	20 Aug 2020 19:49:41

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:47:22', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '3d66b0d0-7896-43ee-8773-ad385ba36325' User entered '97.3'	System	20 Aug 2020 19:49:41

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:47:27', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '3d66b0d0-7896-43ee-8773-ad385ba36325'	System	20 Aug 2020 19:49:41
User entered 'No (N)'	System	20 Aug 2020 19:49:41

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:47:34', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '3d66b0d0-7896-43ee-8773-ad385ba36325'	System	20 Aug 2020 19:49:41
User entered '20 Aug 2020 14:47'	System	20 Aug 2020 19:49:41

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 13:25'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 2'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:02:39', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '32e0f9c5-bb7a-40d3-9bba-050b9475bf8a'	System	21 Aug 2020 17:05:15
User entered 'Yes (Y)'	System	21 Aug 2020 17:05:15

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:02:50', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '32e0f9c5-bb7a-40d3-9bba-050b9475bf8a'	System	21 Aug 2020 17:05:15
User entered '97.7'	System	21 Aug 2020 17:05:15

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:02:55', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '32e0f9c5-bb7a-40d3-9bba-050b9475bf8a'	System	21 Aug 2020 17:05:15
User entered 'No (N)'	System	21 Aug 2020 17:05:15

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:03:02', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '32e0f9c5-bb7a-40d3-9bba-050b9475bf8a'	System	21 Aug 2020 17:05:15
User entered '21 Aug 2020 12:03'	System	21 Aug 2020 17:05:15

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 3'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:13:41', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'ebe8d011-ecca-413d-9d73-4a513cd95845'	System	22 Aug 2020 17:16:12
User entered 'Yes (Y)'	System	22 Aug 2020 17:16:12

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:13:53', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'ebe8d011-ecca-413d-9d73-4a513cd95845'	System	22 Aug 2020 17:16:12
User entered '97.7'	System	22 Aug 2020 17:16:12

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:13:59', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'ebe8d011-ecca-413d-9d73-4a513cd95845'	System	22 Aug 2020 17:16:12
User entered 'No (N)'	System	22 Aug 2020 17:16:12

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:14:04', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'ebe8d011-ecca-413d-9d73-4a513cd95845'	System	22 Aug 2020 17:16:12
User entered '22 Aug 2020 12:14'	System	22 Aug 2020 17:16:12

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 4'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:34:07', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '884bf57e-6327-4876-8786-16e4f18441a6'	System	23 Aug 2020 18:38:39
User entered 'Yes (Y)'	System	23 Aug 2020 18:38:39

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:36:05', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '884bf57e-6327-4876-8786-16e4f18441a6'	System	23 Aug 2020 18:38:39
User entered '97.2'	System	23 Aug 2020 18:38:39

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:36:14', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '884bf57e-6327-4876-8786-16e4f18441a6'	System	23 Aug 2020 18:38:39
User entered 'No (N)'	System	23 Aug 2020 18:38:39

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:36:31', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '884bf57e-6327-4876-8786-16e4f18441a6'	System	23 Aug 2020 18:38:39
User entered '23 Aug 2020 13:36'	System	23 Aug 2020 18:38:39

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 5'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a7b9cdaf-c26c-43d7-b79c-3756067652fe'	System	24 Aug 2020 17:07:43
User entered 'Yes (Y)'	System	24 Aug 2020 17:07:43

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:05:14', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a7b9cdaf-c26c-43d7-b79c-3756067652fe'	System	24 Aug 2020 17:07:43
User entered '98.0'	System	24 Aug 2020 17:07:43

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:05:20', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a7b9cdaf-c26c-43d7-b79c-3756067652fe'	System	24 Aug 2020 17:07:43
User entered 'No (N)'	System	24 Aug 2020 17:07:43

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:05:35', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a7b9cdaf-c26c-43d7-b79c-3756067652fe'	System	24 Aug 2020 17:07:43
User entered '24 Aug 2020 12:05'	System	24 Aug 2020 17:07:43

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 6'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:00:25', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '58ba3c62-cd71-44b7-a334-9054cf48cebb'	System	25 Aug 2020 17:02:57
User entered 'Yes (Y)'	System	25 Aug 2020 17:02:57

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:00:36', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '58ba3c62-cd71-44b7-a334-9054cf48cebb'	System	25 Aug 2020 17:02:57
User entered '97.0'	System	25 Aug 2020 17:02:57

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:00:42', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '58ba3c62-cd71-44b7-a334-9054cf48cebb'	System	25 Aug 2020 17:02:57
User entered 'No (N)'	System	25 Aug 2020 17:02:57

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:00:49', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '58ba3c62-cd71-44b7-a334-9054cf48cebb'	System	25 Aug 2020 17:02:57
User entered '25 Aug 2020 12:00'	System	25 Aug 2020 17:02:57

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 7'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:02:37', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '760568fb-52e3-4b30-b45d-92bb038e4070'	System	26 Aug 2020 17:05:07
User entered 'Yes (Y)'	System	26 Aug 2020 17:05:07

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:02:47', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '760568fb-52e3-4b30-b45d-92bb038e4070'	System	26 Aug 2020 17:05:07
User entered '97.9'	System	26 Aug 2020 17:05:07

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:02:54', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '760568fb-52e3-4b30-b45d-92bb038e4070'	System	26 Aug 2020 17:05:07
User entered 'No (N)'	System	26 Aug 2020 17:05:07

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:02:59', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '760568fb-52e3-4b30-b45d-92bb038e4070'	System	26 Aug 2020 17:05:07
User entered '26 Aug 2020 12:02'	System	26 Aug 2020 17:05:07

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-20T10:25:52', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f2d77a17-2099-4efd-9da0-f015b5b43d53'	System	20 Aug 2020 15:28:07
User entered 'None (1)'	System	20 Aug 2020 15:28:07

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:25:54', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f2d77a17-2099-4efd-9da0-f015b5b43d53'	System	20 Aug 2020 15:28:07
User entered 'No (N)'	System	20 Aug 2020 15:28:07

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:25:55', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f2d77a17-2099-4efd-9da0-f015b5b43d53'	System	20 Aug 2020 15:28:07
User entered 'No (N)'	System	20 Aug 2020 15:28:07

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-20T10:25:57', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f2d77a17-2099-4efd-9da0-f015b5b43d53'	System	20 Aug 2020 15:28:07
User entered 'None (1)'	System	20 Aug 2020 15:28:07

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:25:59', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f2d77a17-2099-4efd-9da0-f015b5b43d53'	System	20 Aug 2020 15:28:07
User entered '20 Aug 2020 10:25'	System	20 Aug 2020 15:28:07

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 10:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:30'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-20T14:47:45', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e6d08d17-24e3-4431-8243-a1e0dadf1b69'	System	20 Aug 2020 19:50:25
User entered 'None (1)'	System	20 Aug 2020 19:50:25

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:47:50', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e6d08d17-24e3-4431-8243-a1e0dadf1b69'	System	20 Aug 2020 19:50:25
User entered 'No (N)'	System	20 Aug 2020 19:50:25

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:47:59', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e6d08d17-24e3-4431-8243-a1e0dadf1b69'	System	20 Aug 2020 19:50:25
User entered 'No (N)'	System	20 Aug 2020 19:50:25

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-20T14:48:13', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e6d08d17-24e3-4431-8243-a1e0dadf1b69'	System	20 Aug 2020 19:50:25
User entered 'None (1)'	System	20 Aug 2020 19:50:25

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:48:17', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e6d08d17-24e3-4431-8243-a1e0dadf1b69'	System	20 Aug 2020 19:50:25
User entered '20 Aug 2020 14:48'	System	20 Aug 2020 19:50:25

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 13:25'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 2'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-21T12:03:18', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a2732d2e-7753-4b61-9400-ebcc0dc7dce7'	System	21 Aug 2020 17:06:04
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 17:06:04

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:03:25', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a2732d2e-7753-4b61-9400-ebcc0dc7dce7'	System	21 Aug 2020 17:06:04
User entered 'No (N)'	System	21 Aug 2020 17:06:04

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:03:38', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a2732d2e-7753-4b61-9400-ebcc0dc7dce7'	System	21 Aug 2020 17:06:04
User entered 'No (N)'	System	21 Aug 2020 17:06:04

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-21T12:03:46', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a2732d2e-7753-4b61-9400-ebcc0dc7dce7'	System	21 Aug 2020 17:06:04
User entered 'None (1)'	System	21 Aug 2020 17:06:04

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:03:56', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a2732d2e-7753-4b61-9400-ebcc0dc7dce7'	System	21 Aug 2020 17:06:04
User entered '21 Aug 2020 12:03'	System	21 Aug 2020 17:06:04

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 3'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-22T12:14:47', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '1b231cd1-c635-4c32-a547-9fbb82348919'	System	22 Aug 2020 17:17:33
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 17:17:33

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:15:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '1b231cd1-c635-4c32-a547-9fbb82348919'	System	22 Aug 2020 17:17:33
User entered 'No (N)'	System	22 Aug 2020 17:17:33

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:15:09', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '1b231cd1-c635-4c32-a547-9fbb82348919'	System	22 Aug 2020 17:17:33
User entered 'No (N)'	System	22 Aug 2020 17:17:33

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-22T12:15:17', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '1b231cd1-c635-4c32-a547-9fbb82348919'	System	22 Aug 2020 17:17:33
User entered 'None (1)'	System	22 Aug 2020 17:17:33

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:15:22', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '1b231cd1-c635-4c32-a547-9fbb82348919'	System	22 Aug 2020 17:17:33
User entered '22 Aug 2020 12:15'	System	22 Aug 2020 17:17:33

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 4'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-23T13:37:28', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '7bee63a8-a5a6-4b7f-9216-1562e5e5596b'	System	23 Aug 2020 18:40:15
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 18:40:15

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:37:37', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '7bee63a8-a5a6-4b7f-9216-1562e5e5596b'	System	23 Aug 2020 18:40:15
User entered 'No (N)'	System	23 Aug 2020 18:40:15

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:37:42', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '7bee63a8-a5a6-4b7f-9216-1562e5e5596b'	System	23 Aug 2020 18:40:15
User entered 'No (N)'	System	23 Aug 2020 18:40:15

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-23T13:37:49', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '7bee63a8-a5a6-4b7f-9216-1562e5e5596b'	System	23 Aug 2020 18:40:15
User entered 'None (1)'	System	23 Aug 2020 18:40:15

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:38:05', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '7bee63a8-a5a6-4b7f-9216-1562e5e5596b'	System	23 Aug 2020 18:40:15
User entered '23 Aug 2020 13:38'	System	23 Aug 2020 18:40:15

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 5'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-24T12:05:42', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a59ea904-150e-415d-9c53-6b0af6b7deae'	System	24 Aug 2020 17:08:11
User entered 'None (1)'	System	24 Aug 2020 17:08:11

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:05:47', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a59ea904-150e-415d-9c53-6b0af6b7deae'	System	24 Aug 2020 17:08:11
User entered 'No (N)'	System	24 Aug 2020 17:08:11

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:05:50', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a59ea904-150e-415d-9c53-6b0af6b7deae'	System	24 Aug 2020 17:08:11
User entered 'No (N)'	System	24 Aug 2020 17:08:11

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-24T12:05:55', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a59ea904-150e-415d-9c53-6b0af6b7deae'	System	24 Aug 2020 17:08:11
User entered 'None (1)'	System	24 Aug 2020 17:08:11

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:06:04', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a59ea904-150e-415d-9c53-6b0af6b7deae'	System	24 Aug 2020 17:08:11
User entered '24 Aug 2020 12:06'	System	24 Aug 2020 17:08:11

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 6'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-25T12:00:56', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'be597e3b-f46b-443b-ba5e-b5e3d8682b4e'	System	25 Aug 2020 17:03:22
User entered 'None (1)'	System	25 Aug 2020 17:03:22

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'be597e3b-f46b-443b-ba5e-b5e3d8682b4e'	System	25 Aug 2020 17:03:22
User entered 'No (N)'	System	25 Aug 2020 17:03:22

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:04', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'be597e3b-f46b-443b-ba5e-b5e3d8682b4e'	System	25 Aug 2020 17:03:22
User entered 'No (N)'	System	25 Aug 2020 17:03:22

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-25T12:01:08', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'be597e3b-f46b-443b-ba5e-b5e3d8682b4e'	System	25 Aug 2020 17:03:22
User entered 'None (1)'	System	25 Aug 2020 17:03:22

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:12', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'be597e3b-f46b-443b-ba5e-b5e3d8682b4e'	System	25 Aug 2020 17:03:22
User entered '25 Aug 2020 12:01'	System	25 Aug 2020 17:03:22

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 7'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-26T12:03:06', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9bbda636-1775-42d9-b456-5cbe1ff96762'	System	26 Aug 2020 17:05:31
User entered 'None (1)'	System	26 Aug 2020 17:05:31

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:10', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9bbda636-1775-42d9-b456-5cbe1ff96762'	System	26 Aug 2020 17:05:31
User entered 'No (N)'	System	26 Aug 2020 17:05:31

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:15', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9bbda636-1775-42d9-b456-5cbe1ff96762'	System	26 Aug 2020 17:05:31
User entered 'No (N)'	System	26 Aug 2020 17:05:31

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-26T12:03:19', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9bbda636-1775-42d9-b456-5cbe1ff96762'	System	26 Aug 2020 17:05:31
User entered 'None (1)'	System	26 Aug 2020 17:05:31

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:23', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9bbda636-1775-42d9-b456-5cbe1ff96762'	System	26 Aug 2020 17:05:31
User entered '26 Aug 2020 12:03'	System	26 Aug 2020 17:05:31

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:26:05', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f75b6b68-1afa-4b0f-b104-12f6a4104be0'	System	20 Aug 2020 15:28:26
User entered 'None (0)'	System	20 Aug 2020 15:28:26

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:26:08', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f75b6b68-1afa-4b0f-b104-12f6a4104be0'	System	20 Aug 2020 15:28:26
User entered 'None (0)'	System	20 Aug 2020 15:28:26

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:26:09', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f75b6b68-1afa-4b0f-b104-12f6a4104be0'	System	20 Aug 2020 15:28:26
User entered 'None (0)'	System	20 Aug 2020 15:28:26

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:26:11', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f75b6b68-1afa-4b0f-b104-12f6a4104be0'	System	20 Aug 2020 15:28:26
User entered 'None (0)'	System	20 Aug 2020 15:28:26

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:26:12', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f75b6b68-1afa-4b0f-b104-12f6a4104be0'	System	20 Aug 2020 15:28:26
User entered 'None (0)'	System	20 Aug 2020 15:28:26

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:26:14', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f75b6b68-1afa-4b0f-b104-12f6a4104be0'	System	20 Aug 2020 15:28:26
User entered 'None (0)'	System	20 Aug 2020 15:28:26

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-20T10:26:15', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f75b6b68-1afa-4b0f-b104-12f6a4104be0'	System	20 Aug 2020 15:28:26
User entered 'No (N)'	System	20 Aug 2020 15:28:26

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:26:19', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f75b6b68-1afa-4b0f-b104-12f6a4104be0'	System	20 Aug 2020 15:28:26
User entered '20 Aug 2020 10:26'	System	20 Aug 2020 15:28:26

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 10:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:30'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:48:23', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'aab260bf-3b46-44c0-a613-d912ce8b9f51'	System	20 Aug 2020 19:51:26
User entered 'None (0)'	System	20 Aug 2020 19:51:26

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:48:30', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'aab260bf-3b46-44c0-a613-d912ce8b9f51'	System	20 Aug 2020 19:51:26
User entered 'None (0)'	System	20 Aug 2020 19:51:26

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:48:34', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'aab260bf-3b46-44c0-a613-d912ce8b9f51'	System	20 Aug 2020 19:51:26
User entered 'None (0)'	System	20 Aug 2020 19:51:26

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:48:38', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'aab260bf-3b46-44c0-a613-d912ce8b9f51'	System	20 Aug 2020 19:51:26
User entered 'None (0)'	System	20 Aug 2020 19:51:26

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:48:43', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'aab260bf-3b46-44c0-a613-d912ce8b9f51'	System	20 Aug 2020 19:51:26
User entered 'None (0)'	System	20 Aug 2020 19:51:26

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:48:47', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'aab260bf-3b46-44c0-a613-d912ce8b9f51'	System	20 Aug 2020 19:51:26
User entered 'None (0)'	System	20 Aug 2020 19:51:26

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-20T14:48:56', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'aab260bf-3b46-44c0-a613-d912ce8b9f51'	System	20 Aug 2020 19:51:26
User entered 'No (N)'	System	20 Aug 2020 19:51:26

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:49:17', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'aab260bf-3b46-44c0-a613-d912ce8b9f51'	System	20 Aug 2020 19:51:26
User entered '20 Aug 2020 14:49'	System	20 Aug 2020 19:51:26

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 13:25'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 2'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:04:05', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'b1858cbb-4c97-4533-bc9d-38798546f56d'	System	21 Aug 2020 17:07:06
User entered 'None (0)'	System	21 Aug 2020 17:07:06

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:04:11', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'b1858cbb-4c97-4533-bc9d-38798546f56d'	System	21 Aug 2020 17:07:06
User entered 'None (0)'	System	21 Aug 2020 17:07:06

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:04:17', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'b1858cbb-4c97-4533-bc9d-38798546f56d'	System	21 Aug 2020 17:07:06
User entered 'None (0)'	System	21 Aug 2020 17:07:06

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:04:22', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'b1858cbb-4c97-4533-bc9d-38798546f56d'	System	21 Aug 2020 17:07:06
User entered 'None (0)'	System	21 Aug 2020 17:07:06

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:04:26', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'b1858cbb-4c97-4533-bc9d-38798546f56d'	System	21 Aug 2020 17:07:06
User entered 'None (0)'	System	21 Aug 2020 17:07:06

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:04:31', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'b1858cbb-4c97-4533-bc9d-38798546f56d'	System	21 Aug 2020 17:07:06
User entered 'None (0)'	System	21 Aug 2020 17:07:06

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-21T12:04:36', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'b1858cbb-4c97-4533-bc9d-38798546f56d'	System	21 Aug 2020 17:07:06
User entered 'No (N)'	System	21 Aug 2020 17:07:06

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:04:42', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'b1858cbb-4c97-4533-bc9d-38798546f56d'	System	21 Aug 2020 17:07:06
User entered '21 Aug 2020 12:04'	System	21 Aug 2020 17:07:06

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 3'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:15:29', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '815d2372-a4fd-4673-bc30-4b8b36d1b3e3'	System	22 Aug 2020 17:18:21
User entered 'None (0)'	System	22 Aug 2020 17:18:21

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:15:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '815d2372-a4fd-4673-bc30-4b8b36d1b3e3'	System	22 Aug 2020 17:18:21
User entered 'None (0)'	System	22 Aug 2020 17:18:21

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:15:40', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '815d2372-a4fd-4673-bc30-4b8b36d1b3e3'	System	22 Aug 2020 17:18:21
User entered 'None (0)'	System	22 Aug 2020 17:18:21

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:15:49', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '815d2372-a4fd-4673-bc30-4b8b36d1b3e3'	System	22 Aug 2020 17:18:21
User entered 'None (0)'	System	22 Aug 2020 17:18:21

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:15:53', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '815d2372-a4fd-4673-bc30-4b8b36d1b3e3'	System	22 Aug 2020 17:18:21
User entered 'None (0)'	System	22 Aug 2020 17:18:21

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:15:57', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '815d2372-a4fd-4673-bc30-4b8b36d1b3e3'	System	22 Aug 2020 17:18:21
User entered 'None (0)'	System	22 Aug 2020 17:18:21

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-22T12:16:06', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '815d2372-a4fd-4673-bc30-4b8b36d1b3e3'	System	22 Aug 2020 17:18:21
User entered 'No (N)'	System	22 Aug 2020 17:18:21

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:16:12', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '815d2372-a4fd-4673-bc30-4b8b36d1b3e3'	System	22 Aug 2020 17:18:21
User entered '22 Aug 2020 12:16'	System	22 Aug 2020 17:18:21

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 4'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:39:07', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5a253040-cf2f-406e-9a8e-aef3ae1a57bd'	System	23 Aug 2020 18:41:22
User entered 'None (0)'	System	23 Aug 2020 18:41:22

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:38:22', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5a253040-cf2f-406e-9a8e-aef3ae1a57bd'	System	23 Aug 2020 18:41:22
User entered 'None (0)'	System	23 Aug 2020 18:41:22

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:38:28', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5a253040-cf2f-406e-9a8e-aef3ae1a57bd'	System	23 Aug 2020 18:41:22
User entered 'None (0)'	System	23 Aug 2020 18:41:22

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:38:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5a253040-cf2f-406e-9a8e-aef3ae1a57bd'	System	23 Aug 2020 18:41:22
User entered 'None (0)'	System	23 Aug 2020 18:41:22

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:38:38', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5a253040-cf2f-406e-9a8e-aef3ae1a57bd'	System	23 Aug 2020 18:41:22
User entered 'None (0)'	System	23 Aug 2020 18:41:22

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:38:41', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5a253040-cf2f-406e-9a8e-aef3ae1a57bd'	System	23 Aug 2020 18:41:22
User entered 'None (0)'	System	23 Aug 2020 18:41:22

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-23T13:38:52', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5a253040-cf2f-406e-9a8e-aef3ae1a57bd'	System	23 Aug 2020 18:41:22
User entered 'No (N)'	System	23 Aug 2020 18:41:22

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:39:14', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5a253040-cf2f-406e-9a8e-aef3ae1a57bd'	System	23 Aug 2020 18:41:22
User entered '23 Aug 2020 13:39'	System	23 Aug 2020 18:41:22

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 5'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:06:13', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '07396209-94ff-40f1-a32d-98d8150498fb'	System	24 Aug 2020 17:09:11
User entered 'None (0)'	System	24 Aug 2020 17:09:11

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:06:24', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '07396209-94ff-40f1-a32d-98d8150498fb'	System	24 Aug 2020 17:09:11
User entered 'None (0)'	System	24 Aug 2020 17:09:11

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:06:30', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '07396209-94ff-40f1-a32d-98d8150498fb'	System	24 Aug 2020 17:09:11
User entered 'None (0)'	System	24 Aug 2020 17:09:11

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:06:35', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '07396209-94ff-40f1-a32d-98d8150498fb'	System	24 Aug 2020 17:09:11
User entered 'None (0)'	System	24 Aug 2020 17:09:11

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:06:40', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '07396209-94ff-40f1-a32d-98d8150498fb'	System	24 Aug 2020 17:09:11
User entered 'None (0)'	System	24 Aug 2020 17:09:11

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:06:45', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '07396209-94ff-40f1-a32d-98d8150498fb'	System	24 Aug 2020 17:09:11
User entered 'None (0)'	System	24 Aug 2020 17:09:11

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-24T12:06:50', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '07396209-94ff-40f1-a32d-98d8150498fb'	System	24 Aug 2020 17:09:11
User entered 'No (N)'	System	24 Aug 2020 17:09:11

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:07:04', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '07396209-94ff-40f1-a32d-98d8150498fb' User entered '24 Aug 2020 12:07'	System	24 Aug 2020 17:09:11

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 6'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:18', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0d76d50a-c60c-41c5-a367-c65fc81b1b65'	System	25 Aug 2020 17:03:53
User entered 'None (0)'	System	25 Aug 2020 17:03:53

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:22', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0d76d50a-c60c-41c5-a367-c65fc81b1b65'	System	25 Aug 2020 17:03:53
User entered 'None (0)'	System	25 Aug 2020 17:03:53

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:26', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0d76d50a-c60c-41c5-a367-c65fc81b1b65'	System	25 Aug 2020 17:03:53
User entered 'None (0)'	System	25 Aug 2020 17:03:53

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:30', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0d76d50a-c60c-41c5-a367-c65fc81b1b65'	System	25 Aug 2020 17:03:53
User entered 'None (0)'	System	25 Aug 2020 17:03:53

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0d76d50a-c60c-41c5-a367-c65fc81b1b65'	System	25 Aug 2020 17:03:53
User entered 'None (0)'	System	25 Aug 2020 17:03:53

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:36', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0d76d50a-c60c-41c5-a367-c65fc81b1b65'	System	25 Aug 2020 17:03:53
User entered 'None (0)'	System	25 Aug 2020 17:03:53

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-25T12:01:40', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0d76d50a-c60c-41c5-a367-c65fc81b1b65'	System	25 Aug 2020 17:03:53
User entered 'No (N)'	System	25 Aug 2020 17:03:53

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:44', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0d76d50a-c60c-41c5-a367-c65fc81b1b65'	System	25 Aug 2020 17:03:53
User entered '25 Aug 2020 12:01'	System	25 Aug 2020 17:03:53

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 7'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:29', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f1267e31-2f56-4121-8377-b2209e262ba4'	System	26 Aug 2020 17:06:06
User entered 'None (0)'	System	26 Aug 2020 17:06:06

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:32', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f1267e31-2f56-4121-8377-b2209e262ba4'	System	26 Aug 2020 17:06:06
User entered 'None (0)'	System	26 Aug 2020 17:06:06

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:36', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f1267e31-2f56-4121-8377-b2209e262ba4'	System	26 Aug 2020 17:06:06
User entered 'None (0)'	System	26 Aug 2020 17:06:06

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:39', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f1267e31-2f56-4121-8377-b2209e262ba4'	System	26 Aug 2020 17:06:06
User entered 'None (0)'	System	26 Aug 2020 17:06:06

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:44', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f1267e31-2f56-4121-8377-b2209e262ba4'	System	26 Aug 2020 17:06:06
User entered 'None (0)'	System	26 Aug 2020 17:06:06

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:47', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f1267e31-2f56-4121-8377-b2209e262ba4'	System	26 Aug 2020 17:06:06
User entered 'None (0)'	System	26 Aug 2020 17:06:06

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-08-26T12:03:52', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f1267e31-2f56-4121-8377-b2209e262ba4'	System	26 Aug 2020 17:06:06
User entered 'No (N)'	System	26 Aug 2020 17:06:06

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:56', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f1267e31-2f56-4121-8377-b2209e262ba4'	System	26 Aug 2020 17:06:06
User entered '26 Aug 2020 12:03'	System	26 Aug 2020 17:06:06

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	28 Aug 2020 16:22:29

US3252261

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	28 Aug 2020 16:22:29

US3252261

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4) (b) (4)	28 Aug 2020 16:22:29

US3252261

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	28 Aug 2020 16:22:29

US3252261

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	28 Aug 2020 16:22:36

US3252261

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Aug 2020 16:22:36

US3252261

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	06 Sep 2020 03:46:25

US3252261

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	06 Sep 2020 03:46:25

US3252261

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4) (b) (4)	06 Sep 2020 03:46:25

US3252261

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	06 Sep 2020 03:46:25

US3252261

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	06 Sep 2020 03:46:31

US3252261

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Sep 2020 03:46:31

US3252261

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	11 Sep 2020 04:12:36

US3252261

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	11 Sep 2020 04:12:36

US3252261

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	11 Sep 2020 04:12:36

US3252261

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	11 Sep 2020 04:12:36

US3252261

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	11 Sep 2020 04:12:41

US3252261

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 04:12:41

US3252261

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	16 Sep 2020 14:42:25

US3252261

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 14:48:48
Amendment Manager: Query text changed to "Visit 2 System Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates."		17 Sep 2020 00:15:33
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'initial date is correct.' (Site from System).	Joanna Gurrola (b) (4) (b) (4)	16 Sep 2020 14:43:24
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	16 Sep 2020 14:42:25
User entered '16 Sep 2020'	Joanna Gurrola (b) (4) (b) (4)	16 Sep 2020 14:42:25

US3252261

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Joanna Gurrola (b) (4) (b) (4)	16 Sep 2020 14:42:25

US3252261

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	16 Sep 2020 14:42:25

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '08:18'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '16 Sep 2020 08:18'	System	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '73'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '16'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '157'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '84'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '10:12'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '16 Sep 2020 10:12'	System	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.1' F	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '63'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '18'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '158'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '78'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:44

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:35

US3252261

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:35

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	16 Sep 2020 15:15:07

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	16 Sep 2020 15:15:07

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	16 Sep 2020 15:15:07

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 15:15:07

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Joanna Gurrola (b) (4) (b) (4)	16 Sep 2020 15:15:07

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '09:42'	Joanna Gurrola (b) (4) (b) (4)	16 Sep 2020 15:15:07

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '16 Sep 2020 09:42'	System	16 Sep 2020 15:15:07

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola (b) (4) (b) (4)	16 Sep 2020 15:15:07

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	16 Sep 2020 15:15:07

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 15:15:07

US3252261

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:35:04

US3252261

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'AWB Number: 914897844496' (Site from DM).	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 23:02:35
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4)	19 Oct 2020 06:36:59
User entered '16 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:35:04

US3252261

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '08:59'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:35:04

US3252261

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '16 Sep 2020 08:59'	System	17 Sep 2020 03:35:04

US3252261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:51:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 16SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Sample dated 16SEP2020 was collected for Visit2 Day 29 using an UNSCHEDULED kit due to unavailable Type A kits.' (Site from DM).	Uche Ehiemua (b) (4)	30 Oct 2020 19:36:22
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 16SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 04:59:30
User entered '16 Sep 2020'	Shannon Moyer (b) (4)	17 Sep 2020 03:35:33

US3252261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:35:33

US3252261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:35:33

US3252261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '08:52'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:35:33

US3252261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '16 Sep 2020 08:52'	System	17 Sep 2020 03:35:33

US3252261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:35:33

US3252261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:35:33

US3252261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:35:33

US3252261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 03:35:33

US3252261

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:35:40

US3252261

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Sep 2020 03:35:40

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:21:04', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '224dd224-ca83-410a-92a9-4d9d80fadb8b'	System	16 Sep 2020 15:23:40
User entered 'Yes (Y)'	System	16 Sep 2020 15:23:40

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:20:47', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '224dd224-ca83-410a-92a9-4d9d80fadb8b'	System	16 Sep 2020 15:23:40
User entered '97.1'	System	16 Sep 2020 15:23:40

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:20:52', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '224dd224-ca83-410a-92a9-4d9d80fadb8b'	System	16 Sep 2020 15:23:40
User entered 'No (N)'	System	16 Sep 2020 15:23:40

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:21:09', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '224dd224-ca83-410a-92a9-4d9d80fadb8b'	System	16 Sep 2020 15:23:40
User entered '16 Sep 2020 10:21'	System	16 Sep 2020 15:23:40

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 10:02'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:32'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:44:28', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9b24b7ba-0087-4665-b6d9-7e21f797fcc2'	System	16 Sep 2020 18:47:20
User entered 'Yes (Y)'	System	16 Sep 2020 18:47:20

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:44:39', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9b24b7ba-0087-4665-b6d9-7e21f797fcc2'	System	16 Sep 2020 18:47:20
User entered '97.2'	System	16 Sep 2020 18:47:20

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:44:43', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9b24b7ba-0087-4665-b6d9-7e21f797fcc2'	System	16 Sep 2020 18:47:20
User entered 'No (N)'	System	16 Sep 2020 18:47:20

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:44:50', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9b24b7ba-0087-4665-b6d9-7e21f797fcc2'	System	16 Sep 2020 18:47:20
User entered '16 Sep 2020 13:44'	System	16 Sep 2020 18:47:20

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 13:27'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 2'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:25:28', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'bc72bdaf-0c7c-4f94-9ef2-9deb1feb5321'	System	18 Sep 2020 00:28:30
User entered 'Yes (Y)'	System	18 Sep 2020 00:28:30

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:25:44', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'bc72bdaf-0c7c-4f94-9ef2-9deb1feb5321'	System	18 Sep 2020 00:28:30
User entered '97.7'	System	18 Sep 2020 00:28:30

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:25:52', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'bc72bdaf-0c7c-4f94-9ef2-9deb1feb5321'	System	18 Sep 2020 00:28:30
User entered 'No (N)'	System	18 Sep 2020 00:28:30

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:25:59', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'bc72bdaf-0c7c-4f94-9ef2-9deb1feb5321'	System	18 Sep 2020 00:28:30
User entered '17 Sep 2020 19:25'	System	18 Sep 2020 00:28:30

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 3'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:52:07', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'd2f438de-b88f-4756-8a94-fdd2eee145fe'	System	18 Sep 2020 17:55:04
User entered 'Yes (Y)'	System	18 Sep 2020 17:55:04

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:52:17', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'd2f438de-b88f-4756-8a94-fdd2eee145fe'	System	18 Sep 2020 17:55:04
User entered '97.7'	System	18 Sep 2020 17:55:04

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:52:27', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'd2f438de-b88f-4756-8a94-fdd2eee145fe'	System	18 Sep 2020 17:55:04
User entered 'No (N)'	System	18 Sep 2020 17:55:04

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:52:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'd2f438de-b88f-4756-8a94-fdd2eee145fe'	System	18 Sep 2020 17:55:04
User entered '18 Sep 2020 12:52'	System	18 Sep 2020 17:55:04

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 4'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:08:35', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '95637890-ab10-4be4-b31f-f972108ba98c'	System	19 Sep 2020 17:12:01
User entered 'Yes (Y)'	System	19 Sep 2020 17:12:01

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:09:11', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '95637890-ab10-4be4-b31f-f972108ba98c'	System	19 Sep 2020 17:12:01
User entered '97.2'	System	19 Sep 2020 17:12:01

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:09:17', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '95637890-ab10-4be4-b31f-f972108ba98c'	System	19 Sep 2020 17:12:01
User entered 'No (N)'	System	19 Sep 2020 17:12:01

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:09:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '95637890-ab10-4be4-b31f-f972108ba98c'	System	19 Sep 2020 17:12:01
User entered '19 Sep 2020 12:09'	System	19 Sep 2020 17:12:01

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 5'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:03', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8a25dd0c-19ae-41d1-aaba-a8895af60031'	System	20 Sep 2020 18:21:52
User entered 'Yes (Y)'	System	20 Sep 2020 18:21:52

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:14', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8a25dd0c-19ae-41d1-aaba-a8895af60031'	System	20 Sep 2020 18:21:52
User entered '97.0'	System	20 Sep 2020 18:21:52

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:18', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8a25dd0c-19ae-41d1-aaba-a8895af60031'	System	20 Sep 2020 18:21:52
User entered 'No (N)'	System	20 Sep 2020 18:21:52

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:23', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8a25dd0c-19ae-41d1-aaba-a8895af60031'	System	20 Sep 2020 18:21:52
User entered '20 Sep 2020 13:19'	System	20 Sep 2020 18:21:52

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 6'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:34:39', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '807cc5f2-3fb6-4a88-bfbb-06cf48fdcc07'	System	21 Sep 2020 18:37:32
User entered 'Yes (Y)'	System	21 Sep 2020 18:37:32

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:34:50', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '807cc5f2-3fb6-4a88-bfbb-06cf48fdcc07'	System	21 Sep 2020 18:37:32
User entered '97.0'	System	21 Sep 2020 18:37:32

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:34:55', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '807cc5f2-3fb6-4a88-bfbb-06cf48fdcc07'	System	21 Sep 2020 18:37:32
User entered 'No (N)'	System	21 Sep 2020 18:37:32

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:35:03', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '807cc5f2-3fb6-4a88-bfbb-06cf48fdcc07'	System	21 Sep 2020 18:37:32
User entered '21 Sep 2020 13:35'	System	21 Sep 2020 18:37:32

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 7'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:13:06', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2f91792f-1a2a-47c3-bcf4-e436f0c437b3'	System	22 Sep 2020 18:16:01
User entered 'Yes (Y)'	System	22 Sep 2020 18:16:01

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:13:16', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2f91792f-1a2a-47c3-bcf4-e436f0c437b3'	System	22 Sep 2020 18:16:01
User entered '96.6'	System	22 Sep 2020 18:16:01

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:13:20', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2f91792f-1a2a-47c3-bcf4-e436f0c437b3'	System	22 Sep 2020 18:16:01
User entered 'No (N)'	System	22 Sep 2020 18:16:01

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:13:31', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2f91792f-1a2a-47c3-bcf4-e436f0c437b3'	System	22 Sep 2020 18:16:01
User entered '22 Sep 2020 13:13'	System	22 Sep 2020 18:16:01

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-16T10:21:24', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '666cbc04-f40a-4b17-9202-d18369e53c69'	System	16 Sep 2020 15:24:32
User entered 'None (1)'	System	16 Sep 2020 15:24:32

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:21:43', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '666cbc04-f40a-4b17-9202-d18369e53c69'	System	16 Sep 2020 15:24:32
User entered 'No (N)'	System	16 Sep 2020 15:24:32

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:21:47', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '666cbc04-f40a-4b17-9202-d18369e53c69'	System	16 Sep 2020 15:24:32
User entered 'No (N)'	System	16 Sep 2020 15:24:32

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-16T10:21:54', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '666cbc04-f40a-4b17-9202-d18369e53c69'	System	16 Sep 2020 15:24:32
User entered 'None (1)'	System	16 Sep 2020 15:24:32

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:22:03', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '666cbc04-f40a-4b17-9202-d18369e53c69'	System	16 Sep 2020 15:24:32
User entered '16 Sep 2020 10:22'	System	16 Sep 2020 15:24:32

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 10:02'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:32'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-16T13:44:58', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8adb1486-0754-4c39-bba1-874ab35c9dd5'	System	16 Sep 2020 18:47:45
User entered 'None (1)'	System	16 Sep 2020 18:47:45

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:04', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8adb1486-0754-4c39-bba1-874ab35c9dd5'	System	16 Sep 2020 18:47:45
User entered 'No (N)'	System	16 Sep 2020 18:47:45

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:08', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8adb1486-0754-4c39-bba1-874ab35c9dd5'	System	16 Sep 2020 18:47:45
User entered 'No (N)'	System	16 Sep 2020 18:47:45

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-16T13:45:12', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8adb1486-0754-4c39-bba1-874ab35c9dd5'	System	16 Sep 2020 18:47:45
User entered 'None (1)'	System	16 Sep 2020 18:47:45

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:16', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8adb1486-0754-4c39-bba1-874ab35c9dd5'	System	16 Sep 2020 18:47:45
User entered '16 Sep 2020 13:45'	System	16 Sep 2020 18:47:45

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 13:27'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 2'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-17T19:26:19', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '17b56a2f-aea2-41ab-9686-258a37d04cd5'	System	18 Sep 2020 00:31:01
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 00:31:01

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:26:54', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '17b56a2f-aea2-41ab-9686-258a37d04cd5'	System	18 Sep 2020 00:31:01
User entered 'Yes (Y)'	System	18 Sep 2020 00:31:01

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:26:51', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '17b56a2f-aea2-41ab-9686-258a37d04cd5' User entered '100'	System	18 Sep 2020 00:31:01

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:26:58', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '17b56a2f-aea2-41ab-9686-258a37d04cd5'	System	18 Sep 2020 00:31:01
User entered 'Yes (Y)'	System	18 Sep 2020 00:31:01

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:28:21', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '17b56a2f-aea2-41ab-9686-258a37d04cd5'	System	18 Sep 2020 00:31:01
User entered '1'	System	18 Sep 2020 00:31:01

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-17T19:28:28', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '17b56a2f-aea2-41ab-9686-258a37d04cd5'	System	18 Sep 2020 00:31:01
User entered 'None (1)'	System	18 Sep 2020 00:31:01

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:28:32', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '17b56a2f-aea2-41ab-9686-258a37d04cd5'	System	18 Sep 2020 00:31:01
User entered '17 Sep 2020 19:28'	System	18 Sep 2020 00:31:01

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 3'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-18T12:52:46', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0849615f-158e-45e5-8fb5-872e62e140f2'	System	18 Sep 2020 17:56:21
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 17:56:21

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:53:09', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0849615f-158e-45e5-8fb5-872e62e140f2'	System	18 Sep 2020 17:56:21
User entered 'Yes (Y)'	System	18 Sep 2020 17:56:21

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:53:19', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0849615f-158e-45e5-8fb5-872e62e140f2'	System	18 Sep 2020 17:56:21
User entered '1'	System	18 Sep 2020 17:56:21

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:53:25', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0849615f-158e-45e5-8fb5-872e62e140f2'	System	18 Sep 2020 17:56:21
User entered 'Yes (Y)'	System	18 Sep 2020 17:56:21

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:53:42', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0849615f-158e-45e5-8fb5-872e62e140f2'	System	18 Sep 2020 17:56:21
User entered '1'	System	18 Sep 2020 17:56:21

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-18T12:53:47', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0849615f-158e-45e5-8fb5-872e62e140f2'	System	18 Sep 2020 17:56:21
User entered 'None (1)'	System	18 Sep 2020 17:56:21

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:53:52', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0849615f-158e-45e5-8fb5-872e62e140f2'	System	18 Sep 2020 17:56:21
User entered '18 Sep 2020 12:53'	System	18 Sep 2020 17:56:21

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 4'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-19T12:09:52', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '97343e23-da89-4943-8d11-3ca88d4a3d9f'	System	19 Sep 2020 17:14:44
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 17:14:44

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:09:59', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '97343e23-da89-4943-8d11-3ca88d4a3d9f'	System	19 Sep 2020 17:14:44
User entered 'Yes (Y)'	System	19 Sep 2020 17:14:44

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:10:26', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '97343e23-da89-4943-8d11-3ca88d4a3d9f' User entered '1'	System	19 Sep 2020 17:14:44

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:10:39', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '97343e23-da89-4943-8d11-3ca88d4a3d9f'	System	19 Sep 2020 17:14:44
User entered 'Yes (Y)'	System	19 Sep 2020 17:14:44

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:11:58', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '97343e23-da89-4943-8d11-3ca88d4a3d9f' User entered '1'	System	19 Sep 2020 17:14:44

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-19T12:12:04', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '97343e23-da89-4943-8d11-3ca88d4a3d9f'	System	19 Sep 2020 17:14:44
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 17:14:44

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:12:14', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '97343e23-da89-4943-8d11-3ca88d4a3d9f' User entered '19 Sep 2020 12:12'	System	19 Sep 2020 17:14:44

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 5'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-20T13:19:29', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f9584b0c-3e95-4cfc-bccd-55d302a1402a'	System	20 Sep 2020 18:22:12
User entered 'None (1)'	System	20 Sep 2020 18:22:12

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f9584b0c-3e95-4cfc-bccd-55d302a1402a'	System	20 Sep 2020 18:22:12
User entered 'No (N)'	System	20 Sep 2020 18:22:12

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:37', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f9584b0c-3e95-4cfc-bccd-55d302a1402a'	System	20 Sep 2020 18:22:12
User entered 'No (N)'	System	20 Sep 2020 18:22:12

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-20T13:19:40', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f9584b0c-3e95-4cfc-bccd-55d302a1402a'	System	20 Sep 2020 18:22:12
User entered 'None (1)'	System	20 Sep 2020 18:22:12

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:44', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f9584b0c-3e95-4cfc-bccd-55d302a1402a'	System	20 Sep 2020 18:22:12
User entered '20 Sep 2020 13:19'	System	20 Sep 2020 18:22:12

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 6'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-21T13:35:11', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '991dfc8f-c75a-4d88-81be-5fd3dbbe72c6'	System	21 Sep 2020 18:38:19
User entered 'None (1)'	System	21 Sep 2020 18:38:19

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:35:22', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '991dfc8f-c75a-4d88-81be-5fd3dbbe72c6'	System	21 Sep 2020 18:38:19
User entered 'No (N)'	System	21 Sep 2020 18:38:19

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:35:26', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '991dfc8f-c75a-4d88-81be-5fd3dbbe72c6'	System	21 Sep 2020 18:38:19
User entered 'No (N)'	System	21 Sep 2020 18:38:19

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-21T13:35:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '991dfc8f-c75a-4d88-81be-5fd3dbbe72c6'	System	21 Sep 2020 18:38:19
User entered 'None (1)'	System	21 Sep 2020 18:38:19

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:35:48', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '991dfc8f-c75a-4d88-81be-5fd3dbbe72c6'	System	21 Sep 2020 18:38:19
User entered '21 Sep 2020 13:35'	System	21 Sep 2020 18:38:19

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 7'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-22T13:13:41', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e41c7cff-a062-4293-a138-090ef062a9fa'	System	22 Sep 2020 18:16:37
User entered 'None (1)'	System	22 Sep 2020 18:16:37

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:13:45', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e41c7cff-a062-4293-a138-090ef062a9fa'	System	22 Sep 2020 18:16:37
User entered 'No (N)'	System	22 Sep 2020 18:16:37

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:13:49', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e41c7cff-a062-4293-a138-090ef062a9fa'	System	22 Sep 2020 18:16:37
User entered 'No (N)'	System	22 Sep 2020 18:16:37

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-22T13:13:58', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e41c7cff-a062-4293-a138-090ef062a9fa'	System	22 Sep 2020 18:16:37
User entered 'None (1)'	System	22 Sep 2020 18:16:37

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:14:09', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e41c7cff-a062-4293-a138-090ef062a9fa'	System	22 Sep 2020 18:16:37
User entered '22 Sep 2020 13:14'	System	22 Sep 2020 18:16:37

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:22:08', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8cc87895-a87a-424d-b078-aa5c81087bb8'	System	16 Sep 2020 15:25:07
User entered 'None (0)'	System	16 Sep 2020 15:25:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:22:13', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8cc87895-a87a-424d-b078-aa5c81087bb8'	System	16 Sep 2020 15:25:07
User entered 'None (0)'	System	16 Sep 2020 15:25:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:22:18', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8cc87895-a87a-424d-b078-aa5c81087bb8'	System	16 Sep 2020 15:25:07
User entered 'None (0)'	System	16 Sep 2020 15:25:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:22:21', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8cc87895-a87a-424d-b078-aa5c81087bb8'	System	16 Sep 2020 15:25:07
User entered 'None (0)'	System	16 Sep 2020 15:25:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:22:25', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8cc87895-a87a-424d-b078-aa5c81087bb8'	System	16 Sep 2020 15:25:07
User entered 'None (0)'	System	16 Sep 2020 15:25:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:22:28', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8cc87895-a87a-424d-b078-aa5c81087bb8'	System	16 Sep 2020 15:25:07
User entered 'None (0)'	System	16 Sep 2020 15:25:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-16T10:22:34', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8cc87895-a87a-424d-b078-aa5c81087bb8'	System	16 Sep 2020 15:25:07
User entered 'No (N)'	System	16 Sep 2020 15:25:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:22:38', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8cc87895-a87a-424d-b078-aa5c81087bb8'	System	16 Sep 2020 15:25:07
User entered '16 Sep 2020 10:22'	System	16 Sep 2020 15:25:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 10:02'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:32'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:22', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '91b7390b-0d14-46c4-9558-898b73540836'	System	16 Sep 2020 18:48:20
User entered 'None (0)'	System	16 Sep 2020 18:48:20

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:25', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '91b7390b-0d14-46c4-9558-898b73540836'	System	16 Sep 2020 18:48:20
User entered 'None (0)'	System	16 Sep 2020 18:48:20

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:28', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '91b7390b-0d14-46c4-9558-898b73540836'	System	16 Sep 2020 18:48:20
User entered 'None (0)'	System	16 Sep 2020 18:48:20

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:32', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '91b7390b-0d14-46c4-9558-898b73540836'	System	16 Sep 2020 18:48:20
User entered 'None (0)'	System	16 Sep 2020 18:48:20

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:35', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '91b7390b-0d14-46c4-9558-898b73540836'	System	16 Sep 2020 18:48:20
User entered 'None (0)'	System	16 Sep 2020 18:48:20

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:39', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '91b7390b-0d14-46c4-9558-898b73540836'	System	16 Sep 2020 18:48:20
User entered 'None (0)'	System	16 Sep 2020 18:48:20

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-16T13:45:43', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '91b7390b-0d14-46c4-9558-898b73540836'	System	16 Sep 2020 18:48:20
User entered 'No (N)'	System	16 Sep 2020 18:48:20

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:48', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '91b7390b-0d14-46c4-9558-898b73540836'	System	16 Sep 2020 18:48:20
User entered '16 Sep 2020 13:45'	System	16 Sep 2020 18:48:20

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 13:27'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 2'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:28:41', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '13bef284-aaaf-4c1a-a376-ff66704bf3cb'	System	18 Sep 2020 00:31:43
User entered 'None (0)'	System	18 Sep 2020 00:31:43

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:28:45', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '13bef284-aaaf-4c1a-a376-ff66704bf3cb'	System	18 Sep 2020 00:31:43
User entered 'None (0)'	System	18 Sep 2020 00:31:43

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:28:53', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '13bef284-aaaf-4c1a-a376-ff66704bf3cb'	System	18 Sep 2020 00:31:43
User entered 'None (0)'	System	18 Sep 2020 00:31:43

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:28:58', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '13bef284-aaaf-4c1a-a376-ff66704bf3cb'	System	18 Sep 2020 00:31:43
User entered 'None (0)'	System	18 Sep 2020 00:31:43

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:29:02', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '13bef284-aaaf-4c1a-a376-ff66704bf3cb'	System	18 Sep 2020 00:31:43
User entered 'None (0)'	System	18 Sep 2020 00:31:43

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:29:05', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '13bef284-aaaf-4c1a-a376-ff66704bf3cb'	System	18 Sep 2020 00:31:43
User entered 'None (0)'	System	18 Sep 2020 00:31:43

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-17T19:29:09', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '13bef284-aaaf-4c1a-a376-ff66704bf3cb'	System	18 Sep 2020 00:31:43
User entered 'No (N)'	System	18 Sep 2020 00:31:43

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:29:13', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '13bef284-aaaf-4c1a-a376-ff66704bf3cb'	System	18 Sep 2020 00:31:43
User entered '17 Sep 2020 19:29'	System	18 Sep 2020 00:31:43

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 3'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:54:03', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e15ccd38-180f-40c9-a997-9969e69f4c1f'	System	18 Sep 2020 17:57:05
User entered 'None (0)'	System	18 Sep 2020 17:57:05

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:54:07', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e15ccd38-180f-40c9-a997-9969e69f4c1f'	System	18 Sep 2020 17:57:05
User entered 'None (0)'	System	18 Sep 2020 17:57:05

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:54:11', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e15ccd38-180f-40c9-a997-9969e69f4c1f'	System	18 Sep 2020 17:57:05
User entered 'None (0)'	System	18 Sep 2020 17:57:05

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:54:15', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e15ccd38-180f-40c9-a997-9969e69f4c1f'	System	18 Sep 2020 17:57:05
User entered 'None (0)'	System	18 Sep 2020 17:57:05

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:54:19', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e15ccd38-180f-40c9-a997-9969e69f4c1f'	System	18 Sep 2020 17:57:05
User entered 'None (0)'	System	18 Sep 2020 17:57:05

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:54:23', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e15ccd38-180f-40c9-a997-9969e69f4c1f'	System	18 Sep 2020 17:57:05
User entered 'None (0)'	System	18 Sep 2020 17:57:05

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-18T12:54:29', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e15ccd38-180f-40c9-a997-9969e69f4c1f'	System	18 Sep 2020 17:57:05
User entered 'No (N)'	System	18 Sep 2020 17:57:05

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:54:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e15ccd38-180f-40c9-a997-9969e69f4c1f'	System	18 Sep 2020 17:57:05
User entered '18 Sep 2020 12:54'	System	18 Sep 2020 17:57:05

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 4'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:12:21', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2e48e6c8-16d9-4d6d-b62f-e8e41ab9a34f'	System	19 Sep 2020 17:15:39
User entered 'None (0)'	System	19 Sep 2020 17:15:39

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:12:26', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2e48e6c8-16d9-4d6d-b62f-e8e41ab9a34f'	System	19 Sep 2020 17:15:39
User entered 'None (0)'	System	19 Sep 2020 17:15:39

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:12:31', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2e48e6c8-16d9-4d6d-b62f-e8e41ab9a34f'	System	19 Sep 2020 17:15:39
User entered 'None (0)'	System	19 Sep 2020 17:15:39

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:12:35', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2e48e6c8-16d9-4d6d-b62f-e8e41ab9a34f'	System	19 Sep 2020 17:15:39
User entered 'None (0)'	System	19 Sep 2020 17:15:39

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:12:41', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2e48e6c8-16d9-4d6d-b62f-e8e41ab9a34f'	System	19 Sep 2020 17:15:39
User entered 'None (0)'	System	19 Sep 2020 17:15:39

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:12:44', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2e48e6c8-16d9-4d6d-b62f-e8e41ab9a34f'	System	19 Sep 2020 17:15:39
User entered 'None (0)'	System	19 Sep 2020 17:15:39

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-19T12:13:03', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2e48e6c8-16d9-4d6d-b62f-e8e41ab9a34f'	System	19 Sep 2020 17:15:39
User entered 'No (N)'	System	19 Sep 2020 17:15:39

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:13:09', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2e48e6c8-16d9-4d6d-b62f-e8e41ab9a34f' User entered '19 Sep 2020 12:13'	System	19 Sep 2020 17:15:39

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 5'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:49', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '61051972-da29-4fef-9fb9-b0a760b7e1bc'	System	20 Sep 2020 18:22:40
User entered 'None (0)'	System	20 Sep 2020 18:22:40

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:52', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '61051972-da29-4fef-9fb9-b0a760b7e1bc'	System	20 Sep 2020 18:22:40
User entered 'None (0)'	System	20 Sep 2020 18:22:40

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:55', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '61051972-da29-4fef-9fb9-b0a760b7e1bc'	System	20 Sep 2020 18:22:40
User entered 'None (0)'	System	20 Sep 2020 18:22:40

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:59', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '61051972-da29-4fef-9fb9-b0a760b7e1bc'	System	20 Sep 2020 18:22:40
User entered 'None (0)'	System	20 Sep 2020 18:22:40

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:20:02', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '61051972-da29-4fef-9fb9-b0a760b7e1bc'	System	20 Sep 2020 18:22:40
User entered 'None (0)'	System	20 Sep 2020 18:22:40

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:20:04', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '61051972-da29-4fef-9fb9-b0a760b7e1bc'	System	20 Sep 2020 18:22:40
User entered 'None (0)'	System	20 Sep 2020 18:22:40

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-20T13:20:08', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '61051972-da29-4fef-9fb9-b0a760b7e1bc'	System	20 Sep 2020 18:22:40
User entered 'No (N)'	System	20 Sep 2020 18:22:40

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:20:11', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '61051972-da29-4fef-9fb9-b0a760b7e1bc'	System	20 Sep 2020 18:22:40
User entered '20 Sep 2020 13:20'	System	20 Sep 2020 18:22:40

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 6'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:35:55', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '27b8f7a8-6926-4bcb-bff1-5667845d075e'	System	21 Sep 2020 18:39:09
User entered 'None (0)'	System	21 Sep 2020 18:39:09

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:36:05', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '27b8f7a8-6926-4bcb-bff1-5667845d075e'	System	21 Sep 2020 18:39:09
User entered 'None (0)'	System	21 Sep 2020 18:39:09

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:36:09', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '27b8f7a8-6926-4bcb-bff1-5667845d075e'	System	21 Sep 2020 18:39:09
User entered 'None (0)'	System	21 Sep 2020 18:39:09

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:36:14', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '27b8f7a8-6926-4bcb-bff1-5667845d075e'	System	21 Sep 2020 18:39:09
User entered 'None (0)'	System	21 Sep 2020 18:39:09

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:36:18', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '27b8f7a8-6926-4bcb-bff1-5667845d075e'	System	21 Sep 2020 18:39:09
User entered 'None (0)'	System	21 Sep 2020 18:39:09

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:36:21', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '27b8f7a8-6926-4bcb-bff1-5667845d075e'	System	21 Sep 2020 18:39:09
User entered 'None (0)'	System	21 Sep 2020 18:39:09

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-21T13:36:26', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '27b8f7a8-6926-4bcb-bff1-5667845d075e'	System	21 Sep 2020 18:39:09
User entered 'No (N)'	System	21 Sep 2020 18:39:09

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:36:40', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '27b8f7a8-6926-4bcb-bff1-5667845d075e'	System	21 Sep 2020 18:39:09
User entered '21 Sep 2020 13:36'	System	21 Sep 2020 18:39:09

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 7'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:14:17', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'cfd66afc-51ae-4820-b8bf-242178634f6d'	System	22 Sep 2020 18:17:27
User entered 'None (0)'	System	22 Sep 2020 18:17:27

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:14:25', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'cfd66afc-51ae-4820-b8bf-242178634f6d'	System	22 Sep 2020 18:17:27
User entered 'None (0)'	System	22 Sep 2020 18:17:27

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:14:30', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'cfd66afc-51ae-4820-b8bf-242178634f6d'	System	22 Sep 2020 18:17:27
User entered 'None (0)'	System	22 Sep 2020 18:17:27

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:14:36', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'cfd66afc-51ae-4820-b8bf-242178634f6d'	System	22 Sep 2020 18:17:27
User entered 'None (0)'	System	22 Sep 2020 18:17:27

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:14:40', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'cfd66afc-51ae-4820-b8bf-242178634f6d'	System	22 Sep 2020 18:17:27
User entered 'None (0)'	System	22 Sep 2020 18:17:27

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:14:44', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'cfd66afc-51ae-4820-b8bf-242178634f6d'	System	22 Sep 2020 18:17:27
User entered 'None (0)'	System	22 Sep 2020 18:17:27

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

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 (907b134012dd7bd7)', Time: '2020-09-22T13:14:49', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'cfd66afc-51ae-4820-b8bf-242178634f6d'	System	22 Sep 2020 18:17:27
User entered 'No (N)'	System	22 Sep 2020 18:17:27

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:14:58', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'cfd66afc-51ae-4820-b8bf-242178634f6d'	System	22 Sep 2020 18:17:27
User entered '22 Sep 2020 13:14'	System	22 Sep 2020 18:17:27

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	24 Sep 2020 05:01:11

US3252261

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	24 Sep 2020 05:01:11

US3252261

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	24 Sep 2020 05:01:11

US3252261

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	24 Sep 2020 05:01:11

US3252261

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	24 Sep 2020 05:01:17

US3252261

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Sep 2020 05:01:17

US3252261

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	01 Oct 2020 06:40:09

US3252261

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	01 Oct 2020 06:40:09

US3252261

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	01 Oct 2020 06:40:09

US3252261

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	01 Oct 2020 06:40:09

US3252261

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	01 Oct 2020 06:40:17

US3252261

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Oct 2020 06:40:17

US3252261

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 05:20:08

US3252261

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '7 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 05:20:08

US3252261

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 05:20:08

US3252261

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 05:20:08

US3252261

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 05:20:12

US3252261

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Oct 2020 05:20:12

US3252261

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 17:10:01

US3252261

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 17:10:01

US3252261

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 17:10:01

US3252261

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	13 Oct 2020 17:10:01

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 17:11:53

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 17:11:53

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '07:31' reason for change: Data Entry Error	Nancy Torrence (b) (4)	13 Oct 2020 23:59:13
User entered '07:26'	Nancy Torrence (b) (4)	13 Oct 2020 17:11:53

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 07:31'	System	13 Oct 2020 23:59:13
User entered '13 Oct 2020 07:26'	System	13 Oct 2020 17:11:53

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 17:11:53

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 17:11:53

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 17:11:53

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 17:11:53

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Oct 2020 17:11:53

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '15'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 17:11:53

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Oct 2020 17:11:53

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '126'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 17:11:53

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 17:11:53

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '85'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 17:11:53

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 17:11:53

US3252261

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:44

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 17:12:02

US3252261

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 17:12:02

US3252261

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 17:12:23

US3252261

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 17:12:23

US3252261

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '07:49'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 17:12:23

US3252261

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 07:49'	System	13 Oct 2020 17:12:23

US3252261

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 17:12:29

US3252261

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Oct 2020 17:12:29

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 64'	System	20 Aug 2020 15:03:52

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[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 (907b134012dd7bd7)', Time: '2020-10-21T10:03:54', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '3d6e0bf5-1e43-44de-b5d2-f317361c9df1'	System	21 Oct 2020 15:06:56
User entered 'No (N)'	System	21 Oct 2020 15:06:56

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2020-10-21T10:04:01', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '3d6e0bf5-1e43-44de-b5d2-f317361c9df1'	System	21 Oct 2020 15:06:56
User entered 'No (N)'	System	21 Oct 2020 15:06:56

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-10-21T10:04:09', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '3d6e0bf5-1e43-44de-b5d2-f317361c9df1'	System	21 Oct 2020 15:06:56
User entered '21 Oct 2020 10:04:09'	System	21 Oct 2020 15:06:56

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 15:03:52

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 71'	System	20 Aug 2020 15:03:52

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[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 (907b134012dd7bd7)', Time: '2020-10-27T20:56:29', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5b44d435-a158-439e-bb8e-bb6b9ba1a1c9'	System	28 Oct 2020 01:59:23
User entered 'No (N)'	System	28 Oct 2020 01:59:23

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2020-10-27T20:56:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5b44d435-a158-439e-bb8e-bb6b9ba1a1c9'	System	28 Oct 2020 01:59:23
User entered 'No (N)'	System	28 Oct 2020 01:59:23

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-10-27T20:56:38', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5b44d435-a158-439e-bb8e-bb6b9ba1a1c9'	System	28 Oct 2020 01:59:23
User entered '27 Oct 2020 20:56:38'	System	28 Oct 2020 01:59:23

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 15:03:52

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 78'	System	20 Aug 2020 15:03:52

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[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 (907b134012dd7bd7)', Time: '2020-11-03T08:50:06', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '542d316d-24ef-4829-872c-2adfdcecc3c44'	System	03 Nov 2020 14:53:38
User entered 'No (N)'	System	03 Nov 2020 14:53:38

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2020-11-03T08:50:13', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '542d316d-24ef-4829-872c-2adfdccc3c44'	System	03 Nov 2020 14:53:38
User entered 'No (N)'	System	03 Nov 2020 14:53:38

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-11-03T08:50:52', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '542d316d-24ef-4829-872c-2adfdccc3c44'	System	03 Nov 2020 14:53:38
User entered '03 Nov 2020 08:50:52'	System	03 Nov 2020 14:53:38

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 15:03:52

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 92'	System	20 Aug 2020 15:03:52

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[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 (907b134012dd7bd7)', Time: '2020-11-17T09:32:42', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '258f7ba1-d57b-4852-aae3-593617182f0d'	System	17 Nov 2020 15:35:40
User entered 'No (N)'	System	17 Nov 2020 15:35:40

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2020-11-17T09:32:48', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '258f7ba1-d57b-4852-aae3-593617182f0d'	System	17 Nov 2020 15:35:40
User entered 'No (N)'	System	17 Nov 2020 15:35:40

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-11-17T09:32:53', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '258f7ba1-d57b-4852-aae3-593617182f0d'	System	17 Nov 2020 15:35:40
User entered '17 Nov 2020 09:32:53'	System	17 Nov 2020 15:35:40

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 15:03:52

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 15:03:52
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '17 Oct 2020 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '21 Oct 2020 23:59'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '24 Oct 2020 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '28 Oct 2020 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '31 Oct 2020 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '04 Nov 2020 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '07 Nov 2020 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '11 Nov 2020 23:59'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '14 Nov 2020 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '18 Nov 2020 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[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 (907b134012dd7bd7)', Time: '2020-11-21T15:03:50', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0ff0eb94-0240-4937-8e3d-7007c03a1d23'	System	21 Nov 2020 21:07:12
User entered 'No (N)'	System	21 Nov 2020 21:07:12

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2020-11-21T15:03:56', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0ff0eb94-0240-4937-8e3d-7007c03a1d23'	System	21 Nov 2020 21:07:12
User entered 'No (N)'	System	21 Nov 2020 21:07:12

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-11-21T15:04:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0ff0eb94-0240-4937-8e3d-7007c03a1d23'	System	21 Nov 2020 21:07:12
User entered '21 Nov 2020 15:04:00'	System	21 Nov 2020 21:07:12

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:33:16

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 23:33:16

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 02:56:44

US3252261

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 02:56:44

US3252261

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 02:56:44

US3252261

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 02:56:44

US3252261

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 02:56:49

US3252261

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 02:56:49

US3252261

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:51:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	11 Nov 2020 21:40:59
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:45:47

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:41
User entered 'USA-US108-2020-mRNA-1273-P301000017'	System	12 Nov 2020 19:39:37
User entered 'New'	(b) (4), (b) (6)	12 Nov 2020 19:39:37

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure, LLT: Heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 21:47:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 21:47:37
Data point term sent to Coder	System	11 Nov 2020 21:46:28
User entered 'Heart Failure'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Nov 2020'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '3 Nov 2020'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Severity](#)

Audit	User	Time (GMT)
Query 'PV Query: Since the subject was hospitalized for the event of heart failure, appropriate severity grade should be grade 4 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' answered with 'Severity grade has been updated appropriately. ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 21:49:15
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 21:48:05
User opened query 'PV Query: Since the subject was hospitalized for the event of heart failure, appropriate severity grade should be grade 4 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:46:02
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered 'I'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Nov 2020'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '3 Nov 2020'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Query 'PV Query: As the last dose of study drug was given on 16 Sep 2020, please update the action taken from none to not applicable.' answered with 'Data has been updated' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 21:49:43
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 21:49:28
User opened query 'PV Query: As the last dose of study drug was given on 16 Sep 2020, please update the action taken from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:45:45
User entered 'None (NONE)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[None](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #14-16 start/stop dates were not during this AE timeframe. Please review and reconcile AE and CM start and stop dates as appropriate or update action taken. ' answered with 'Concomitant medication start dates reviewed and updated.' (Site from DM).	Joanna Gurrola (b) (4) (b) (4)	24 Nov 2020 22:45:02
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #14-16 start/stop dates were not during this AE timeframe. Please review and reconcile AE and CM start and stop dates as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	23 Nov 2020 04:32:25
User entered 'I'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Narrative](#)

Audit	User	Time (GMT)
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 22:58:42
User opened query 'PV Query: Was a cause (or possible cause) for the heart failure identified?' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:46:33
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 21:46:27
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:46:20
User entered 'Patient admitted because of shortness of breath, she stayed in the hospital for 3 days and got released. We will request medical records.'	Joanna Gurrola (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 21:45:45

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:51:44

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:49:08

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:51:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:51:22
Data point term sent to Coder	System	21 Aug 2020 14:50:35
User entered 'Metropolol'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	11 Nov 2020 21:46:11
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '9 Nov 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	11 Nov 2020 21:46:11
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:52:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:52:24
Data point term sent to Coder	System	21 Aug 2020 14:51:39
User entered 'Simvastatin'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:02

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:02

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hyperlipidemia'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:02

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:02

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:02

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:02

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:02

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:02

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:02

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:02

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:02

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:02

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:02

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:02

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:02

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:51:02

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:51:02

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:51:02

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM, PRODUCTSYNONYM: LOSARTAN/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:53:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:53:26
Data point term sent to Coder	System	21 Aug 2020 14:52:40
User entered 'Losartan/Hydrochlorothiazide'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100/25'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	11 Nov 2020 21:46:28
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '9 Nov 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	11 Nov 2020 21:46:28
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:53:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:53:54
Data point term sent to Coder	System	21 Aug 2020 14:52:42
User entered 'Amlodipine'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	11 Nov 2020 21:46:51
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '9 Nov 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	11 Nov 2020 21:46:51
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:55:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:55:16
Data point term sent to Coder	System	21 Aug 2020 14:53:45
User entered 'Levothyroxine'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:15
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:15

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypothyroidism'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:15

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '112'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:15

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Dose Unit=Other; MCG. Please review and verify if the Dose Unit can be changed to ug as this is one of the pre-listed options in the Unit field. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:44:40
Query 'Per DM CLR: Dose Unit=Other; MCG. Please review and verify if the Dose Unit can be changed to ug as this is one of the pre-listed options in the Unit field. If yes, please update accordingly.' answered with 'Dose unit updated' (Site from DM).	Uche Ehiemua (b) (4)	30 Sep 2020 14:36:49
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	30 Sep 2020 14:36:38
User opened query 'Per DM CLR: Dose Unit=Other; MCG. Please review and verify if the Dose Unit can be changed to ug as this is one of the pre-listed options in the Unit field. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 10:51:48
User entered 'Other (OTHER)'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:15

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Uche Ehiemua (b) (4)	30 Sep 2020 14:36:38
User entered 'mcg'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:15

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:15

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:15

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:15

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:15

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:15

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:15

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:15

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:15

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:15

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:53:15

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:53:15

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:53:15

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:55:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:55:54
Data point term sent to Coder	System	21 Aug 2020 14:54:47
User entered 'Montelukast'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:55
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:55

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

[Indication](#)

Audit	User	Time (GMT)
User entered 'Asthma'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:55

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:55

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:55

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:55

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:55

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:55

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:55

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:55

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 1995'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:55

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:55

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:55

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:55

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:53:55

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:53:55

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:53:55

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:53:55

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: BABY ASPIRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:55:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:55:17
Data point term sent to Coder	System	21 Aug 2020 14:54:48
User entered 'Baby Asprin'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:54:43

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:54:43

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

[Indication](#)

Audit	User	Time (GMT)
User entered 'Heart Health'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:54:43

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:54:43

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:54:43

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:54:43

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:54:43

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:54:43

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:54:43

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:54:43

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2013'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:54:43

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:54:43

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:54:43

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:54:43

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:54:43

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:54:43

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:54:43

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:54:43

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:57:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:57:17
Data point term sent to Coder	System	21 Aug 2020 14:55:53
User entered 'Pantoprazole'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:55:31

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:55:31

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

[Indication](#)

Audit	User	Time (GMT)
User entered 'Gastroesophageal reflux disease'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:55:31

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:55:31

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:55:31

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:55:31

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:55:31

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:55:31

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:55:31

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:55:31

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2020'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:55:31

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:55:31

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:55:31

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:55:31

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:55:31

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:55:31

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:55:31

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:55:31

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:57:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:57:18
Data point term sent to Coder	System	21 Aug 2020 14:56:54
User entered 'Cetirizine'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:08
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:08

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

[Indication](#)

Audit	User	Time (GMT)
User entered 'Seasonal allergy'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:08

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:08

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:08

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:08

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:08

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:08

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:08

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:08

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:08

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:08

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:08

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:08

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:08

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:56:08

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:56:08

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:56:08

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 11:39:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 11:39:38
Data point term sent to Coder	System	21 Aug 2020 14:56:56
User entered 'OTC Vitamin D'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:49

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:49

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

[Indication](#)

Audit	User	Time (GMT)
User entered 'dietary supplement'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:49

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:45:23
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Dosage update as per patient.' (Site from DM).	Uche Ehiemua (b) (4)	30 Sep 2020 14:38:35
User entered '5000' reason for change: Data Entry Error	Uche Ehiemua (b) (4)	30 Sep 2020 14:38:18
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 10:52:29
User entered '1'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:49

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'TU (IU)' reason for change: Data Entry Uche Ehiemua Error	(b) (4)	30 Sep 2020 14:38:18
User entered 'tablet (TABLET)'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:49

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:49

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:49

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:49

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:49

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:49

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:49

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:49

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:49

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:49

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:56:49

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:56:49

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:56:49

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:56:49

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 11:39:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 11:39:38
Data point term sent to Coder	System	21 Aug 2020 15:05:26
Data point term sent to Coder	System	21 Aug 2020 15:02:17
User entered 'OTC Vitamin B12'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:02:06

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:02:06

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 15:04:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 15:04:27
User entered 'dietary supplement' reason for change: Shannon Moyer Data Entry Error	(b) (4)	21 Aug 2020 15:04:27
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 15:02:06
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 15:02:06

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:02:06

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:02:06

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:02:06

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:02:06

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:02:06

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:02:06

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:02:06

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:02:06

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:02:06

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:02:06

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:02:06

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:02:06

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:02:06

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:02:06

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:02:06

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 05:52:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 05:52:45
Data point term sent to Coder	System	21 Aug 2020 15:03:19
User entered 'OTC Multivitamin'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:04

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:04

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

[Indication](#)

Audit	User	Time (GMT)
User entered 'Dietary supplement'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:04

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:04

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:04

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:04

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:04

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:04

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:04

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:04

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:04

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:04

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:04

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:04

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:04

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:03:04

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:03:04

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:03:04

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:05:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:05:15
Data point term sent to Coder	System	21 Aug 2020 15:04:25
User entered 'Advair'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:56

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:56

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

[Indication](#)

Audit	User	Time (GMT)
User entered 'Asthma'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:56

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '230/21'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:56

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Dose Unit=Other; MCG. Please review and verify if the Dose Unit can be changed to ug as this is one of the pre-listed options in the Unit field. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:46:15
Query 'Per DM CLR: Dose Unit=Other; MCG. Please review and verify if the Dose Unit can be changed to ug as this is one of the pre-listed options in the Unit field. If yes, please update accordingly.' answered with 'Dose unit updated.' (Site from DM).	Uche Ehiemua (b) (4)	30 Sep 2020 14:40:08
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	30 Sep 2020 14:39:48
User opened query 'Per DM CLR: Dose Unit=Other; MCG. Please review and verify if the Dose Unit can be changed to ug as this is one of the pre-listed options in the Unit field. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 10:50:56
User entered 'Other (OTHER)'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:56

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Uche Ehiemua (b) (4)	30 Sep 2020 14:39:48
User entered 'mcg'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:56

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:46:19
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'frequency updated as per patient' (Site from DM).	Uche Ehiemua (b) (4) (b) (4)	30 Sep 2020 14:40:43
User entered 'as needed (PRN)' reason for change: Data Entry Error	Uche Ehiemua (b) (4) (b) (4)	30 Sep 2020 14:39:48
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 10:51:19
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:56

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:56

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:56

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:56

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:56

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:56

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:56

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:56

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 15:03:56

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:39:48
User entered '1'	System	21 Aug 2020 15:03:56

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:39:48
User entered '1'	System	21 Aug 2020 15:03:56

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:39:48
User entered '804 (804)'	System	21 Aug 2020 15:03:56

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: OLMESARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:54:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:54:07
Data point term sent to Coder	System	11 Nov 2020 21:49:36
User entered 'Olmesartan'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

[Indication](#)

Audit	User	Time (GMT)
User entered 'Heart Failure'	Joanna Gurrola (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	(b) (4)	
	Joanna Gurrola (b) (4)	11 Nov 2020 21:47:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Joanna Gurrola (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Joanna Gurrola (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	(b) (4)	
	Joanna Gurrola (b) (4)	11 Nov 2020 21:47:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Joanna Gurrola (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	(b) (4)	
	Joanna Gurrola (b) (4)	11 Nov 2020 21:47:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Joanna Gurrola (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	(b) (4)	
	Joanna Gurrola (b) (4)	11 Nov 2020 21:47:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '03 Nov 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	24 Nov 2020 22:44:16
Query 'Per CDM: Please note, there is no AE that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the AE eCRF as appropriate or, provide AE record number this indication pertains to. Thanks.' answered with 'AE has been recorded and matches the timeframe. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 22:03:47
User opened query 'Per CDM: Please note, there is no AE that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the AE eCRF as appropriate or, provide AE record number this indication pertains to. Thanks.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 10:58:05
User entered '9 Nov 2020'	Joanna Gurrola (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4)	11 Nov 2020 21:48:48
	(b) (4)	
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	11 Nov 2020 21:47:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4)	11 Nov 2020 21:48:48
	(b) (4)	
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	11 Nov 2020 21:47:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:03:12
User entered 'No (N)'	Joanna Gurrola (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 21:50:36
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 21:50:36
Data point term sent to Coder	System	11 Nov 2020 21:49:36
User entered 'Furosemide'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

[Indication](#)

Audit	User	Time (GMT)
User entered 'Heart Failure'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '03 Nov 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	24 Nov 2020 22:44:25
User entered '9 Nov 2020'	Joanna Gurrola (b) (4)	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:04:01
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 21:51:36
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 21:51:36
Data point term sent to Coder	System	11 Nov 2020 21:50:37
User entered 'Carvedilol'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

[Indication](#)

Audit	User	Time (GMT)
User entered 'Heart Failure'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '12'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

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

Audit	User	Time (GMT)
User entered '03 Nov 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	24 Nov 2020 22:44:34
User entered '9 Nov 2020'	Joanna Gurrola (b) (4)	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:04:18
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:51:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:51:44

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:48:49

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'USA-US108-2020-MRNA-1273-P301000017'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'Yes (Y)'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'Yes (Y)'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'Joel'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'Solis'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered '5201 N. 10th Street'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'Mcallen'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'TX'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'carmpa'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	12 Nov 2020 19:39:58

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 19:39:58

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'USA-US108-2020-MRNA-1273-P301000017'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'Yes (Y)'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'Yes (Y)'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'Joel'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'Solis'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered '5201 N. 10th Street'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'Mcallen'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'TX'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'carmpa'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	12 Nov 2020 19:39:58

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 19:39:58

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:51:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '12/Nov/2020 19:39'	System	12 Nov 2020 19:39:58

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:51:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 19:39:58