

US3252166 (Prod: Centex Studies Inc)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:51:06

All time stamps listed in this document are displayed in GMT

US3252166

Form: Participant Creation

Generated On: 26 Nov 2020 10:51:06

[Participant ID](#)

US3252166

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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 10:51:06

Date of Birth (MMM yyyy)	(b) (6) 1970
Age	50
Age Units	YEARS
Age (Derived)	50
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 10:51:06

Date of Informed Consent (<i>dd MMM yyyy</i>)	13 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 10:51:06

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:51:06

[Were any significant conditions reported?](#)

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:06

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:06

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

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:06

Condition	HYPERTRIGLYCERIDEMIA
Start date (dd MMM yyyy)	UN JAN 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 (4)

Generated On: 26 Nov 2020 10:51:06

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

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:06

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:06

Condition	ALLERGY TO PETS
Start date (dd MMM yyyy)	UN JAN 2010
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 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:06

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN JAN 2007
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 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:06

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	UN OCT 2007
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 OCT 2007
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2007
Start Year (derived)	2007
Stop Month and Year (derived)	OCT 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:06

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	UN OCT 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN OCT 2002
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2002
Start Year (derived)	2002
Stop Month and Year (derived)	OCT 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:51:06

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

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:51:06

Condition	CHOLECYSTITIS
Start date (dd MMM yyyy)	UN JAN 2007
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 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:51:06

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:53 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 15:53
Height (<i>xxx.x</i>)	60.0 in
Weight (<i>xxx.x</i>)	225.2 lb
BMI (<i>xxx.x</i>)	44.07332 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 10:51:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 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 10:51:06

Date of assessment (<i>dd MMM yyyy</i>)	13 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 2017
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 10:51:06

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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 10:51:06

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 143874

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 10:51:06

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 10:51:06

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)	13 AUG 2020
Time of assessment (00:00-23:59)	15:53 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 15:53
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 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 10:51:06

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)	13 AUG 2020
Time of assessment (00:00-23:59)	17:54 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 17:54
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

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 10:51:06

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) 13 AUG 2020

What was the treatment time? (00:00-23:59) 17:04 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 17:04

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 10:51:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	13 AUG 2020
Collection time (<i>00:00-23:59</i>)	16:44 (24 HR)
Collection date and time (derived)	13 AUG 2020 16:44

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:51:06

Collection date (<i>dd MMM yyyy</i>)			13 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	16:33	13 AUG 2020 16:33
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

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 10:51:06

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

98.7 °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

13 AUG 2020 18:04

PC Open Date & Time

13 AUG 2020 17:24

PC Close Date & Time

13 AUG 2020 19:54

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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	13 AUG 2020 20:52
PC Open Date & Time	13 AUG 2020 20:49
PC Close Date & Time	14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

14 AUG 2020 14:48

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:06

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

15 AUG 2020 16:41

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 14:17

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:06

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

17 AUG 2020 17:33

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:06

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

19 AUG 2020 07:11

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:06

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

96.2 °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 AUG 2020 22:04

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 18:05

PC Open Date & Time

13 AUG 2020 17:24

PC Close Date & Time

13 AUG 2020 19:54

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 20:53

PC Open Date & Time

13 AUG 2020 20:49

PC Close Date & Time

14 AUG 2020 11:59

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 14:50

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 16:41

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 14:18

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 17:33

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:06

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

19 AUG 2020 07:11

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 22:05

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 18:05
PC Open Date & Time	13 AUG 2020 17:24
PC Close Date & Time	13 AUG 2020 19:54

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 20:54
PC Open Date & Time	13 AUG 2020 20:49
PC Close Date & Time	14 AUG 2020 11:59

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

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 ☒

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 14:51
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

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 ☒

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 16:42
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

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 ☒

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 14:18
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

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 ☒

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 17:34
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

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 ☒

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 07:11
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

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 ☒

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 22:05
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3252166

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

Was Contact Attempted?

Yes ☒

No ☐

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

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252166

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252166

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252166

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

Was Contact Attempted?

Yes ☒

No ☐

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

5 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252166

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252166

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

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)	10 SEP 2020
Time of assessment (00:00-23:59)	14:23 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 14:23
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

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)	10 SEP 2020
Time of assessment (00:00-23:59)	16:15 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 16:15
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3252166

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

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.

US3252166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

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)	10 SEP 2020
What was the treatment time? (00:00-23:59)	15:29 (24 HR)
Treatment Date and Time (derived)	10 SEP 2020 15:29
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

US3252166

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	10 SEP 2020
Collection time (<i>00:00-23:59</i>)	14:32 (24 HR)
Collection date and time (derived)	10 SEP 2020 14:32

US3252166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:51:06

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:28	10 SEP 2020 14:28
Nasopharyngeal Swab 2	No		

US3252166

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 16:16

PC Open Date & Time

10 SEP 2020 15:49

PC Close Date & Time

10 SEP 2020 18:19

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.0 °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	10 SEP 2020 19:15
PC Open Date & Time	10 SEP 2020 19:14
PC Close Date & Time	11 SEP 2020 11:59

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:06

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 15:46

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:06

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

97.5 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

12 SEP 2020 12:01

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:06

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

94.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 20:36

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 21:05

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 19:40

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:06

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

97.2 °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 20:52

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 16:16

PC Open Date & Time

10 SEP 2020 15:49

PC Close Date & Time

10 SEP 2020 18:19

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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

10 SEP 2020 19:16

PC Open Date & Time

10 SEP 2020 19:14

PC Close Date & Time

11 SEP 2020 11:59

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:06

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

11 SEP 2020 15:47

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:06

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

12 SEP 2020 12:01

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:06

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

13 SEP 2020 20:36

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:06

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

14 SEP 2020 21:05

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:06

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

15 SEP 2020 19:40

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:06

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

16 SEP 2020 20:52

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 16:17
PC Open Date & Time	10 SEP 2020 15:49
PC Close Date & Time	10 SEP 2020 18:19

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 19:17
PC Open Date & Time	10 SEP 2020 19:14
PC Close Date & Time	11 SEP 2020 11:59

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

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 ☒

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 15:47
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

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 ☒

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

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 ☒

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 20:37
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

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 ☒

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 21:06
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

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 ☒

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 19:41
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

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 ☒

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 20:53
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3252166

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

Was Contact Attempted?

Yes ☒

No ☐

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

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252166

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252166

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

Was Contact Attempted?

Yes ☒

No ☐

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

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252166

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252166

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

Was Contact Attempted?

Yes ☒

No ☐

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

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252166

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252166

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	09:33 (24 HR)
Vital Signs Date and Time (derived)	10 OCT 2020 09:33
Temperature (<i>xxx.x</i>)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252166

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

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.

US3252166

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	10 OCT 2020
Collection time (<i>00:00-23:59</i>)	09:54 (24 HR)
Collection date and time (derived)	10 OCT 2020 09:54

US3252166

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	13 OCT 2020 00:02:44
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

21 OCT 2020 08:22:49

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

27 OCT 2020 06:10:22

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

12 NOV 2020 22:36:22

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 99

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

No ☒

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 07:03:05

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Close Date & Time](#)

14 OCT 2020 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Open Date & Time](#)

31 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2020 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 20:27:38

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐ 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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
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Patient Cloud Close Date & Time	30 DEC 2020 23:59
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US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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="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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 159

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Open Date & Time](#)

16 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 166

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

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

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

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

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

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

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 187

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

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

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

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

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

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

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Open Date & Time](#)

13 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

27 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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="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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Open Date & Time](#)

13 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 222

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

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

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

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

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

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

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐
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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 250

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Open Date & Time](#)

17 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Open Date & Time](#)

24 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐
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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐
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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐
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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐
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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
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Patient Cloud Close Date & Time	17 NOV 2021 23:59
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US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐
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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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="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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2022 00:01
Patient Cloud Close Date & Time	29 JUN 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

Was Contact Attempted?

Yes ☒

No ☐

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

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252166

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252166

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3252166

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:51:06

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"/>

US3252166

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:51:06

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3252166

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:51:06

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

AEID	USA-US108-2020-MRNA-1273-P30 1000015
Adverse event	THYROIDECTOMY
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)	01 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)	1 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	30 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	1 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)	346 of 1830

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

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 HAD SCHEDULE THYROIDECTOMY AND WAS OBSERVED FOR 36 HOURS AT THE HOSPITAL.
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

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

AEID	
Adverse event	HYPOTHYROIDISM
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)	30 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	348 of 1830

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

AEID	
Adverse event	METASTATIC PAPILLARY THYROID CARCINOMA
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)	22 SEP 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)	30 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
v6.020 DTW (1102)	
350 of 1830	

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:51:06

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

Yes ☒

No ☐

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

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

	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 JAN 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"/>

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

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 JAN 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"/>

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

Name of Medication	METOPROLOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	100
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input 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"/>

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

Name of Medication	METFORMIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	TYPE 2 DIABETES
Dose per administration	1000/500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	
1000 IN THE MORNING AND 500 AT NIGHT	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HEADACHE
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input 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"/>

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

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)	12 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 SEP 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	INFLUENZA VIRUS
Dose per administration	180
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	MCG
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input checked="" type="radio"/>

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

	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)		26 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		26 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPOTHYROIDISM
Dose per administration	150
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	MCG
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:51:06

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3252166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:51:06

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
22 SEP 2020	LEFT CERVICAL LYMPH NODE EXCISION	Diagnostic	

US3252166

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:51:06

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

US3252166

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

SAEID	USA-US108-2020-MRNA-1273-P301000015
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

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:51:06

SAEID	USA-US108-2020-MRNA-1273-P301000015
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)	06/NOV/2020 22:31
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

US3252166 (Prod: Centex Studies Inc)

US3252166

Form: Participant Creation

Generated On: 26 Nov 2020 10:51:06

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3252166'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	13 Aug 2020 21:14:07

US3252166

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:10:07

US3252166

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 21:14:08

US3252166

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

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)	14 Aug 2020 20:10:07

US3252166

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	14 Aug 2020 20:10:07

US3252166

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1970'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 21:14:09

US3252166

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

[Age](#)

Audit	User	Time (GMT)
User entered '50'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3252166

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	14 Aug 2020 20:10:42

US3252166

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '50'	System	13 Aug 2020 21:30:31

US3252166

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3252166

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3252166

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

[White](#)

Audit	User	Time (GMT)
User entered 'I'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3252166

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3252166

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3252166

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3252166

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3252166

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3252166

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3252166

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3252166

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3252166

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:06

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 21:30:31

US3252166

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	13 Aug 2020 21:30:31

US3252166

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2020'	System	13 Aug 2020 21:30:31

US3252166

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:06

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	13 Aug 2020 21:30:31

US3252166

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 21:30:31

US3252166

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:30:31

US3252166

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:06

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:30:31

US3252166

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:06

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:30:31

US3252166

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:06

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 21:14:08

US3252166

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:06

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Aug 2020 21:30:41

US3252166

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:51:06

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 21:30:41

US3252166

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:51:06

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:11:04

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:11:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:11:24
Data point term sent to Coder	System	14 Aug 2020 20:11:51
User entered 'type 2 diabetes'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:11:38

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:11:38

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:11:38

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:11:38

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:11:38

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:11:38

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	14 Aug 2020 20:11:38

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2010'	System	14 Aug 2020 20:11:38

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:11:38

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:11:38

US3252166

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:06

[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)	15 Aug 2020 00:11:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:11:30
Data point term sent to Coder	System	14 Aug 2020 20:12:52
User entered 'hypertension'	Shannon Moyer (b) (4)	14 Aug 2020 20:11:53
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:11:53

US3252166

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:11:53

US3252166

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:11:53

US3252166

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:11:53

US3252166

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:11:53

US3252166

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	14 Aug 2020 20:11:53

US3252166

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2010'	System	14 Aug 2020 20:11:53

US3252166

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:11:53

US3252166

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:11:53

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated triglycerides, PT: Hypertriglyceridaemia, LLT: Hypertriglyceridemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:11:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:11:30
Data point term sent to Coder	System	14 Aug 2020 20:12:53
User entered 'hypertriglyceridemia'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:12:29

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'un Jan 2020'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:12:29

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:12:29

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:12:29

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:12:29

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:12:29

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	14 Aug 2020 20:12:29

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2020'	System	14 Aug 2020 20:12:29

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:12:29

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:12:29

US3252166

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:11:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:11:31
Data point term sent to Coder	System	14 Aug 2020 20:13:54
User entered 'environmental allergies'	Shannon Moyer (b) (4)	14 Aug 2020 20:13:02
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:13:02

US3252166

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:13:02

US3252166

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:13:02

US3252166

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:13:02

US3252166

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:13:02

US3252166

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	14 Aug 2020 20:13:02

US3252166

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2015'	System	14 Aug 2020 20:13:02

US3252166

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:13:02

US3252166

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:13:02

US3252166

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:06

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:20:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:20:20
Data point term sent to Coder	System	21 Aug 2020 17:20:03
User entered 'seasonal allergies'	Shannon Moyer (b) (4)	21 Aug 2020 17:19:17
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'un Jan 2010'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:19:17

US3252166

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:19:17

US3252166

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Sep 2020 19:36:02
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 17:19:17

US3252166

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Joanna Gurrola (b) (4)	21 Sep 2020 19:36:02
User entered 'un Jan 2010'	Shannon Moyer (b) (4)	21 Aug 2020 17:19:17

US3252166

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:19:17

US3252166

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	21 Aug 2020 17:19:17

US3252166

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2010'	System	21 Aug 2020 17:19:17

US3252166

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 19:36:02
User entered 'Jan 2010'	System	21 Aug 2020 17:19:17

US3252166

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 19:36:02
User entered '2010'	System	21 Aug 2020 17:19:17

US3252166

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:06

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to animal, LLT: Allergy to animals - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 22:28:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 22:28:19
Data point term sent to Coder	System	21 Aug 2020 17:21:05
User entered 'allergy to pets'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:20:05

US3252166

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'un Jan 2010'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:20:05

US3252166

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:20:05

US3252166

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:20:05

US3252166

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'un Jan 2010'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:20:05

US3252166

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:20:05

US3252166

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	21 Aug 2020 17:20:05

US3252166

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2010'	System	21 Aug 2020 17:20:05

US3252166

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	21 Aug 2020 17:20:05

US3252166

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2010'	System	21 Aug 2020 17:20:05

US3252166

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:06

[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)	29 Oct 2020 20:54:17
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 'Patient was contacted and medical history was updated.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 21:10:33
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)	14 Sep 2020 05:25:59
User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:22:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:22:18
Data point term sent to Coder	System	21 Aug 2020 17:21:05
User entered 'cholecystectomy'	Shannon Moyer (b) (4)	21 Aug 2020 17:20:29

US3252166

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'un Jan 2007'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:20:29

US3252166

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:20:29

US3252166

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:20:29

US3252166

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'un Jan 2007'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:20:29

US3252166

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:20:29

US3252166

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	21 Aug 2020 17:20:29

US3252166

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2007'	System	21 Aug 2020 17:20:29

US3252166

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	21 Aug 2020 17:20:29

US3252166

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2007'	System	21 Aug 2020 17:20:29

US3252166

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:22:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:22:18
Data point term sent to Coder	System	21 Aug 2020 17:21:07
User entered 'cesarean section'	Shannon Moyer (b) (4)	21 Aug 2020 17:20:52
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'un Oct 2007'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:20:52

US3252166

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:20:52

US3252166

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:20:52

US3252166

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'un Oct 2007'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:20:52

US3252166

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:20:52

US3252166

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Oct 2007'	System	21 Aug 2020 17:20:52

US3252166

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2007'	System	21 Aug 2020 17:20:52

US3252166

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Oct 2007'	System	21 Aug 2020 17:20:52

US3252166

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2007'	System	21 Aug 2020 17:20:52

US3252166

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:22:19
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 17:22:19
Data point term sent to Coder	System	21 Aug 2020 17:22:10
User entered 'cesarean section'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:21:22

US3252166

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'un Oct 2002'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:21:22

US3252166

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:21:22

US3252166

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:21:22

US3252166

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'un Oct 2002'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:21:22

US3252166

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:21:22

US3252166

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Oct 2002'	System	21 Aug 2020 17:21:22

US3252166

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2002'	System	21 Aug 2020 17:21:22

US3252166

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Oct 2002'	System	21 Aug 2020 17:21:22

US3252166

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2002'	System	21 Aug 2020 17:21:22

US3252166

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:51:06

[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)	29 Oct 2020 20:54:20
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 'Patient was contacted and medical history was updated. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 21:10:48
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)	14 Sep 2020 05:27:13
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) (b) (4)	21 Aug 2020 17:23:16
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 17:23:16
Data point term sent to Coder	System	21 Aug 2020 17:22:14
User entered 'hysterectomy'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:21:50

US3252166

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'un Jan 2017'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:21:50

US3252166

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:51:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:21:50

US3252166

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:51:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:21:50

US3252166

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'un Jan 2017'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:21:50

US3252166

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:51:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:21:50

US3252166

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	21 Aug 2020 17:21:50

US3252166

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2017'	System	21 Aug 2020 17:21:50

US3252166

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	21 Aug 2020 17:21:50

US3252166

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2017'	System	21 Aug 2020 17:21:50

US3252166

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:51:06

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 21:11:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 21:11:46
Data point term sent to Coder	System	29 Sep 2020 21:10:32
User entered 'Cholecystitis'	(b) (4), (b) (6)	29 Sep 2020 21:09:40

US3252166

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'UN Jan 2007'	(b) (4), (b) (6)	29 Sep 2020 21:09:40

US3252166

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:51:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 21:09:40

US3252166

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:51:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 21:09:40

US3252166

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'UN Jan 2007'	(b) (4), (b) (6)	29 Sep 2020 21:09:40

US3252166

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:51:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 21:09:40

US3252166

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	29 Sep 2020 21:09:40

US3252166

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2007'	System	29 Sep 2020 21:09:40

US3252166

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	29 Sep 2020 21:09:40

US3252166

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2007'	System	29 Sep 2020 21:09:40

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:51:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine myoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 21:11:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 21:11:46
Data point term sent to Coder	System	29 Sep 2020 21:10:32
User entered 'Uterine myoma'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'UN Jan 2017'	(b) (4), (b) (6)	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:51:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:51:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'UN Jan 2017'	(b) (4), (b) (6)	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:51:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2017'	System	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '2017'	System	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '15:53'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '13 Aug 2020 15:53'	System	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '60.0' in	Shannon Moyer (b) (4)	14 Aug 2020 20:15:56
DataPoint set to visible.	(b) (4) System	13 Aug 2020 21:30:41

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '225.2' lb	Shannon Moyer (b) (4)	14 Aug 2020 20:15:56
DataPoint set to visible.	(b) (4) System	13 Aug 2020 21:30:41

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
Amendment Manager: User entered '44.07332'	System	16 Sep 2020 23:56:25
User entered '44.1'	System	14 Aug 2020 20:15:56
DataPoint set to visible.	System	13 Aug 2020 21:30:41

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	14 Aug 2020 20:15:56
DataPoint set to visible.	System	13 Aug 2020 21:30:41

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:22:22
User entered '98.8' F	Shannon Moyer (b) (4)	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	23 Aug 2020 21:44:55
User entered 'Other (Other)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:22:22
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	23 Aug 2020 21:44:55
User entered 'not done' reason for change: Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:22:22
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:22:22
User entered '76'	Shannon Moyer (b) (4)	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:22:22
User entered '16'	Shannon Moyer (b) (4)	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:22:22
User entered '122'	Shannon Moyer (b) (4)	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:22:22
User entered '79'	Shannon Moyer (b) (4)	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:16:16

US3252166

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

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)	13 Sep 2020 15:29:46
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		11 Sep 2020 22:06:36
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:16:16

US3252166

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:17:18

US3252166

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:06

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:17:18

US3252166

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Surgically sterile (SURGICALLY STERILE)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:17:18

US3252166

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:17:18

US3252166

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, date of surgery= UNK 2017. However, MH HYSTERECTOMY start date is JAN 2017. Review and reconcile Dates as appropriate. Else, provide comment. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 17:55:51
Query 'Per DM CLR: Note, date of surgery= UNK 2017. However, MH HYSTERECTOMY start date is JAN 2017. Review and reconcile Dates as appropriate. Else, provide comment. ' answered with 'Corrected' (Site from DM).	Nancy Torrence (b) (4)	05 Sep 2020 21:19:45
User entered 'UN Jan 2017' reason for change: Data Entry Error	(b) (4)	05 Sep 2020 21:19:34
User opened query 'Per DM CLR: Note, date of surgery= UNK 2017. However, MH HYSTERECTOMY start date is JAN 2017. Review and reconcile Dates as appropriate. Else, provide comment. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 03:32:07
User entered 'un UNK 2017'	Shannon Moyer (b) (4)	14 Aug 2020 20:17:18

US3252166

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:06

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:17:18

US3252166

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:17:18

US3252166

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:51:06

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:17:18

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

Other

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:18:01

US3252166

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:18:01

US3252166

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

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)	14 Aug 2020 20:18:01

US3252166

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	14 Aug 2020 20:18:01

US3252166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	13 Aug 2020 21:29:31

US3252166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:06

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 04:23:06
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:23:06
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 21:29:31
User entered '143874' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 21:29:31

US3252166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Aug 2020 21:29:31

US3252166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:48

US3252166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:48

US3252166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 21:31:48

US3252166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:06

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 21:31:48

US3252166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:06

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:48

US3252166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4)	02 Oct 2020 03:23:59
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:28
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:11:02

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:06

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:22:51
User entered '60.0' in	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:06

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:22:51
User entered '225.2' lb	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:06

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:22:51
User entered '60.0' in	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:06

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:22:51
User entered '225.2' lb	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '15:53'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '13 Aug 2020 15:53'	System	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.8' F	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '16'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '122'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '79'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:06

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:22:51
User entered '60.0' in	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:06

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:22:51
User entered '225.2' lb	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 17:23:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 17:23:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:23:52
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 20:19:52
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:23:52
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '17:54' reason for change: Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:23:52
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '13 Aug 2020 17:54'	System	21 Aug 2020 17:23:52
User entered empty.	System	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F reason for change: Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:23:52
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:23:52
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76' reason for change: Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:23:52
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Aug 2020 17:23:52
User entered empty.	System	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '15' reason for change: Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:23:52
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Aug 2020 17:23:52
User entered empty.	System	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '136' reason for change: Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:23:52
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 17:23:52
User entered empty.	System	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '85' reason for change: Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:23:52
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 17:23:52
User entered empty.	System	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:24:24
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	14 Aug 2020 20:20:14

US3252166

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:24:24
User entered '13 Aug 2020'	Shannon Moyer (b) (4)	14 Aug 2020 20:20:14

US3252166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Aug 2020 21:46:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Aug 2020 21:46:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	23 Aug 2020 21:46:13
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 23:03:14
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	13 Aug 2020 23:03:14

US3252166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	13 Aug 2020 23:03:14

US3252166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

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)	13 Aug 2020 23:03:14

US3252166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	23 Aug 2020 21:46:13
User entered empty.	System	13 Aug 2020 23:03:14

US3252166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	13 Aug 2020 23:03:14

US3252166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '17:04'	Joanna Gurrola (b) (4) (b) (4)	13 Aug 2020 23:03:14

US3252166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '13 Aug 2020 17:04'	System	13 Aug 2020 23:03:14

US3252166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola (b) (4) (b) (4)	13 Aug 2020 23:03:14

US3252166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	23 Aug 2020 21:46:13
User entered empty.	System	13 Aug 2020 23:03:14

US3252166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	23 Aug 2020 21:46:13
User entered empty.	System	13 Aug 2020 23:03:14

US3252166

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:21:25

US3252166

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:21:25

US3252166

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '16:44'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:21:25

US3252166

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '13 Aug 2020 16:44'	System	14 Aug 2020 20:21:25

US3252166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:51:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:21:42

US3252166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:06

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:21:42

US3252166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:06

[Was the sample collected?](#)

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

US3252166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '16:33'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:21:42

US3252166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '13 Aug 2020 16:33'	System	14 Aug 2020 20:21:42

US3252166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:06

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:21:42

US3252166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:21:42

US3252166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:06

Collection time (00:00 - 23:59)

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

US3252166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:21:42

US3252166

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:21:46

US3252166

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 20:21:46

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T18:03:54', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a86129aa-a43f-47a1-b3bc-518f5282b705'	System	13 Aug 2020 23:04:40
User entered 'Yes (Y)'	System	13 Aug 2020 23:04:40

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T18:04:21', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a86129aa-a43f-47a1-b3bc-518f5282b705'	System	13 Aug 2020 23:04:40
User entered '98.7'	System	13 Aug 2020 23:04:40

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T18:04:05', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a86129aa-a43f-47a1-b3bc-518f5282b705'	System	13 Aug 2020 23:04:40
User entered 'No (N)'	System	13 Aug 2020 23:04:40

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T18:04:37', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a86129aa-a43f-47a1-b3bc-518f5282b705'	System	13 Aug 2020 23:04:40
User entered '13 Aug 2020 18:04'	System	13 Aug 2020 23:04:40

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 17:24'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 19:54'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T20:51:57', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '198e1217-ddd9-4f59-ad60-605db9a39f34'	System	14 Aug 2020 01:52:28
User entered 'Yes (Y)'	System	14 Aug 2020 01:52:28

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T20:52:05', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '198e1217-ddd9-4f59-ad60-605db9a39f34' User entered '97.3'	System	14 Aug 2020 01:52:28

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T20:52:10', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '198e1217-ddd9-4f59-ad60-605db9a39f34'	System	14 Aug 2020 01:52:28
User entered 'No (N)'	System	14 Aug 2020 01:52:28

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T20:52:25', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '198e1217-ddd9-4f59-ad60-605db9a39f34'	System	14 Aug 2020 01:52:28
User entered '13 Aug 2020 20:52'	System	14 Aug 2020 01:52:28

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 20:49'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 2'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-14T14:48:41', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'ac6f316a-7352-49d2-aee3-a32d319a9d96'	System	14 Aug 2020 19:49:02
User entered 'Yes (Y)'	System	14 Aug 2020 19:49:02

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-14T14:48:46', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'ac6f316a-7352-49d2-aee3-a32d319a9d96'	System	14 Aug 2020 19:49:02
User entered '98.1'	System	14 Aug 2020 19:49:02

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-14T14:48:51', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'ac6f316a-7352-49d2-aee3-a32d319a9d96'	System	14 Aug 2020 19:49:02
User entered 'No (N)'	System	14 Aug 2020 19:49:02

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-14T14:48:58', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'ac6f316a-7352-49d2-ae3-a32d319a9d96'	System	14 Aug 2020 19:49:02
User entered '14 Aug 2020 14:48'	System	14 Aug 2020 19:49:02

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 3'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-15T16:41:20', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'd5490dc1-d69e-4965-8f4e-03f77f9654f1'	System	15 Aug 2020 21:41:36
User entered 'Yes (Y)'	System	15 Aug 2020 21:41:36

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-15T16:41:26', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'd5490dc1-d69e-4965-8f4e-03f77f9654f1' User entered '97.7'	System	15 Aug 2020 21:41:36

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-15T16:41:30', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'd5490dc1-d69e-4965-8f4e-03f77f9654f1'	System	15 Aug 2020 21:41:36
User entered 'No (N)'	System	15 Aug 2020 21:41:36

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-15T16:41:34', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'd5490dc1-d69e-4965-8f4e-03f77f9654f1' User entered '15 Aug 2020 16:41'	System	15 Aug 2020 21:41:36
	System	15 Aug 2020 21:41:36

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 4'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-16T14:17:22', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '7a9e2074-0850-4a7d-a574-409bce33d0d2'	System	16 Aug 2020 19:17:36
User entered 'Yes (Y)'	System	16 Aug 2020 19:17:36

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-16T14:17:26', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '7a9e2074-0850-4a7d-a574-409bce33d0d2'	System	16 Aug 2020 19:17:36
User entered '96.4'	System	16 Aug 2020 19:17:36

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-16T14:17:31', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '7a9e2074-0850-4a7d-a574-409bce33d0d2'	System	16 Aug 2020 19:17:36
User entered 'No (N)'	System	16 Aug 2020 19:17:36

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-16T14:17:34', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '7a9e2074-0850-4a7d-a574-409bce33d0d2'	System	16 Aug 2020 19:17:36
User entered '16 Aug 2020 14:17'	System	16 Aug 2020 19:17:36

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 5'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-17T17:33:26', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'c9548636-52f1-4c8e-9463-be87f042e453'	System	17 Aug 2020 22:33:42
User entered 'Yes (Y)'	System	17 Aug 2020 22:33:42

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-17T17:33:31', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'c9548636-52f1-4c8e-9463-be87f042e453'	System	17 Aug 2020 22:33:42
User entered '97.0'	System	17 Aug 2020 22:33:42

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-17T17:33:34', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'c9548636-52f1-4c8e-9463-be87f042e453'	System	17 Aug 2020 22:33:42
User entered 'No (N)'	System	17 Aug 2020 22:33:42

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-17T17:33:37', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'c9548636-52f1-4c8e-9463-be87f042e453'	System	17 Aug 2020 22:33:42
User entered '17 Aug 2020 17:33'	System	17 Aug 2020 22:33:42

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 6'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T07:10:55', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8d217a0f-cd46-4d33-8a4b-be5f5587a165'	System	19 Aug 2020 12:11:22
User entered 'Yes (Y)'	System	19 Aug 2020 12:11:22

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T07:11:13', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8d217a0f-cd46-4d33-8a4b-be5f5587a165'	System	19 Aug 2020 12:11:22
User entered '97.0'	System	19 Aug 2020 12:11:22

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T07:11:17', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8d217a0f-cd46-4d33-8a4b-be5f5587a165'	System	19 Aug 2020 12:11:22
User entered 'No (N)'	System	19 Aug 2020 12:11:22

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T07:11:20', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8d217a0f-cd46-4d33-8a4b-be5f5587a165'	System	19 Aug 2020 12:11:22
User entered '19 Aug 2020 07:11'	System	19 Aug 2020 12:11:22

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 7'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T22:04:06', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '197dc22b-c2fa-4826-9360-ff763b232a23'	System	20 Aug 2020 03:05:01
User entered 'Yes (Y)'	System	20 Aug 2020 03:05:01

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T22:04:11', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '197dc22b-c2fa-4826-9360-ff763b232a23'	System	20 Aug 2020 03:05:01
User entered '96.2'	System	20 Aug 2020 03:05:01

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T22:04:54', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '197dc22b-c2fa-4826-9360-ff763b232a23'	System	20 Aug 2020 03:05:01
User entered 'No (N)'	System	20 Aug 2020 03:05:01

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T22:04:57', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '197dc22b-c2fa-4826-9360-ff763b232a23'	System	20 Aug 2020 03:05:01
User entered '19 Aug 2020 22:04'	System	20 Aug 2020 03:05:01

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T18:04:49', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '1fb4071f-4f70-4975-ae6b-932943b2f0fe'	System	13 Aug 2020 23:05:12
User entered 'None (1)'	System	13 Aug 2020 23:05:12

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T18:05:02', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '1fb4071f-4f70-4975-ae6b-932943b2f0fe'	System	13 Aug 2020 23:05:12
User entered 'No (N)'	System	13 Aug 2020 23:05:12

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T18:05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '1fb4071f-4f70-4975-ae6b-932943b2f0fe'	System	13 Aug 2020 23:05:12
User entered 'No (N)'	System	13 Aug 2020 23:05:12

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T18:05:05', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '1fb4071f-4f70-4975-ae6b-932943b2f0fe'	System	13 Aug 2020 23:05:12
User entered 'None (1)'	System	13 Aug 2020 23:05:12

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T18:05:10', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '1fb4071f-4f70-4975-ae6b-932943b2f0fe'	System	13 Aug 2020 23:05:12
User entered '13 Aug 2020 18:05'	System	13 Aug 2020 23:05:12

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 17:24'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 19:54'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T20:52:49', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9da3aee8-227b-425c-883f-1f092ac71b0a'	System	14 Aug 2020 01:53:21
User entered 'None (1)'	System	14 Aug 2020 01:53:21

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T20:52:55', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9da3aee8-227b-425c-883f-1f092ac71b0a'	System	14 Aug 2020 01:53:21
User entered 'No (N)'	System	14 Aug 2020 01:53:21

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T20:52:59', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9da3aee8-227b-425c-883f-1f092ac71b0a'	System	14 Aug 2020 01:53:21
User entered 'No (N)'	System	14 Aug 2020 01:53:21

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T20:53:11', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9da3aee8-227b-425c-883f-1f092ac71b0a'	System	14 Aug 2020 01:53:21
User entered 'None (1)'	System	14 Aug 2020 01:53:21

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T20:53:18', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9da3aee8-227b-425c-883f-1f092ac71b0a'	System	14 Aug 2020 01:53:21
User entered '13 Aug 2020 20:53'	System	14 Aug 2020 01:53:21

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 20:49'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 2'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:06

[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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-14T14:49:33', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '0d42b62e-b662-4ce7-936a-5b3e16571ca4'	System	14 Aug 2020 19:50:21
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 19:50:21

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-14T14:49:38', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '0d42b62e-b662-4ce7-936a-5b3e16571ca4'	System	14 Aug 2020 19:50:21
User entered 'No (N)'	System	14 Aug 2020 19:50:21

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-14T14:49:56', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '0d42b62e-b662-4ce7-936a-5b3e16571ca4'	System	14 Aug 2020 19:50:21
User entered 'No (N)'	System	14 Aug 2020 19:50:21

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-14T14:50:07', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '0d42b62e-b662-4ce7-936a-5b3e16571ca4'	System	14 Aug 2020 19:50:21
User entered 'None (1)'	System	14 Aug 2020 19:50:21

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-14T14:50:17', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '0d42b62e-b662-4ce7-936a-5b3e16571ca4'	System	14 Aug 2020 19:50:21
User entered '14 Aug 2020 14:50'	System	14 Aug 2020 19:50:21

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 3'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-15T16:41:42', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '441daed0-e791-4734-a968-3ce6979934f3'	System	15 Aug 2020 21:42:00
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 21:42:00

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-15T16:41:46', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '441daed0-e791-4734-a968-3ce6979934f3'	System	15 Aug 2020 21:42:00
User entered 'No (N)'	System	15 Aug 2020 21:42:00

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-15T16:41:49', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '441daed0-e791-4734-a968-3ce6979934f3'	System	15 Aug 2020 21:42:00
User entered 'No (N)'	System	15 Aug 2020 21:42:00

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-15T16:41:54', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '441daed0-e791-4734-a968-3ce6979934f3'	System	15 Aug 2020 21:42:00
User entered 'None (1)'	System	15 Aug 2020 21:42:00

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-15T16:41:57', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '441daed0-e791-4734-a968-3ce6979934f3' User entered '15 Aug 2020 16:41'	System	15 Aug 2020 21:42:00
	System	15 Aug 2020 21:42:00

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 4'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:06

[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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-16T14:17:43', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8d9e3721-ea25-4072-9823-b0abff717802'	System	16 Aug 2020 19:18:27
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 19:18:27

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-16T14:17:46', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8d9e3721-ea25-4072-9823-b0abff717802'	System	16 Aug 2020 19:18:27
User entered 'No (N)'	System	16 Aug 2020 19:18:27

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-16T14:17:48', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8d9e3721-ea25-4072-9823-b0abff717802'	System	16 Aug 2020 19:18:27
User entered 'No (N)'	System	16 Aug 2020 19:18:27

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-16T14:18:01', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8d9e3721-ea25-4072-9823-b0abff717802'	System	16 Aug 2020 19:18:27
User entered 'None (1)'	System	16 Aug 2020 19:18:27

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-16T14:18:25', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8d9e3721-ea25-4072-9823-b0abff717802'	System	16 Aug 2020 19:18:27
User entered '16 Aug 2020 14:18'	System	16 Aug 2020 19:18:27

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 5'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:06

[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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-17T17:33:41', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8c0f76be-e144-4dcc-92d4-5eae6d2bcc8f'	System	17 Aug 2020 22:33:52
User entered 'None (1)'	System	17 Aug 2020 22:33:52

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-17T17:33:44', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8c0f76be-e144-4dcc-92d4-5eae6d2bcc8f'	System	17 Aug 2020 22:33:52
User entered 'No (N)'	System	17 Aug 2020 22:33:52

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-17T17:33:46', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8c0f76be-e144-4dcc-92d4-5eae6d2bcc8f'	System	17 Aug 2020 22:33:52
User entered 'No (N)'	System	17 Aug 2020 22:33:52

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-17T17:33:48', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8c0f76be-e144-4dcc-92d4-5eae6d2bcc8f'	System	17 Aug 2020 22:33:52
User entered 'None (1)'	System	17 Aug 2020 22:33:52

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-17T17:33:51', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8c0f76be-e144-4dcc-92d4-5eae6d2bcc8f' User entered '17 Aug 2020 17:33'	System	17 Aug 2020 22:33:52
	System	17 Aug 2020 22:33:52

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 6'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:06

[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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T07:11:24', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '04b77034-3381-41da-b2cc-d9e04bbc785f'	System	19 Aug 2020 12:11:40
User entered 'None (1)'	System	19 Aug 2020 12:11:40

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T07:11:27', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '04b77034-3381-41da-b2cc-d9e04bbc785f'	System	19 Aug 2020 12:11:40
User entered 'No (N)'	System	19 Aug 2020 12:11:40

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T07:11:30', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '04b77034-3381-41da-b2cc-d9e04bbc785f'	System	19 Aug 2020 12:11:40
User entered 'No (N)'	System	19 Aug 2020 12:11:40

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T07:11:32', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '04b77034-3381-41da-b2cc-d9e04bbc785f'	System	19 Aug 2020 12:11:40
User entered 'None (1)'	System	19 Aug 2020 12:11:40

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T07:11:35', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '04b77034-3381-41da-b2cc-d9e04bbc785f'	System	19 Aug 2020 12:11:40
User entered '19 Aug 2020 07:11'	System	19 Aug 2020 12:11:40

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 7'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:06

[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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T22:05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cdabe56f-f8d7-4dd9-948e-a849e4c2919d'	System	20 Aug 2020 03:05:17
User entered 'None (1)'	System	20 Aug 2020 03:05:17

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T22:05:05', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cdabe56f-f8d7-4dd9-948e-a849e4c2919d'	System	20 Aug 2020 03:05:17
User entered 'No (N)'	System	20 Aug 2020 03:05:17

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T22:05:08', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cdabe56f-f8d7-4dd9-948e-a849e4c2919d'	System	20 Aug 2020 03:05:17
User entered 'No (N)'	System	20 Aug 2020 03:05:17

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T22:05:10', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cdabe56f-f8d7-4dd9-948e-a849e4c2919d'	System	20 Aug 2020 03:05:17
User entered 'None (1)'	System	20 Aug 2020 03:05:17

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T22:05:15', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cdabe56f-f8d7-4dd9-948e-a849e4c2919d'	System	20 Aug 2020 03:05:17
User entered '19 Aug 2020 22:05'	System	20 Aug 2020 03:05:17

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T18:05:20', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a7ec5037-0d14-4db1-b460-5b9a1519edfe'	System	13 Aug 2020 23:05:41
User entered 'No interference with activity (1)'	System	13 Aug 2020 23:05:41

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T18:05:24', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a7ec5037-0d14-4db1-b460-5b9a1519edfe' User entered 'None (0)'	System	13 Aug 2020 23:05:41

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T18:05:26', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a7ec5037-0d14-4db1-b460-5b9a1519edfe'	System	13 Aug 2020 23:05:41
User entered 'None (0)'	System	13 Aug 2020 23:05:41

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T18:05:28', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a7ec5037-0d14-4db1-b460-5b9a1519edfe'	System	13 Aug 2020 23:05:41
User entered 'None (0)'	System	13 Aug 2020 23:05:41

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T18:05:30', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a7ec5037-0d14-4db1-b460-5b9a1519edfe'	System	13 Aug 2020 23:05:41
User entered 'None (0)'	System	13 Aug 2020 23:05:41

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T18:05:31', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a7ec5037-0d14-4db1-b460-5b9a1519edfe' User entered 'None (0)'	System	13 Aug 2020 23:05:41
	System	13 Aug 2020 23:05:41

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T18:05:33', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a7ec5037-0d14-4db1-b460-5b9a1519edfe' User entered 'No (N)'	System	13 Aug 2020 23:05:41

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T18:05:38', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a7ec5037-0d14-4db1-b460-5b9a1519edfe' User entered '13 Aug 2020 18:05'	System	13 Aug 2020 23:05:41
	System	13 Aug 2020 23:05:41

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 17:24'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 19:54'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T20:53:32', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9ef3b1aa-82d6-40f3-a240-5c4a2dda93b7'	System	14 Aug 2020 01:54:17
User entered 'None (0)'	System	14 Aug 2020 01:54:17

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T20:53:42', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9ef3b1aa-82d6-40f3-a240-5c4a2dda93b7'	System	14 Aug 2020 01:54:17
User entered 'None (0)'	System	14 Aug 2020 01:54:17

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T20:53:47', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9ef3b1aa-82d6-40f3-a240-5c4a2dda93b7'	System	14 Aug 2020 01:54:17
User entered 'None (0)'	System	14 Aug 2020 01:54:17

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T20:53:51', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9ef3b1aa-82d6-40f3-a240-5c4a2dda93b7'	System	14 Aug 2020 01:54:17
User entered 'None (0)'	System	14 Aug 2020 01:54:17

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T20:53:54', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9ef3b1aa-82d6-40f3-a240-5c4a2dda93b7'	System	14 Aug 2020 01:54:17
User entered 'None (0)'	System	14 Aug 2020 01:54:17

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T20:53:56', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9ef3b1aa-82d6-40f3-a240-5c4a2dda93b7'	System	14 Aug 2020 01:54:17
User entered 'None (0)'	System	14 Aug 2020 01:54:17

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T20:54:08', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9ef3b1aa-82d6-40f3-a240-5c4a2dda93b7'	System	14 Aug 2020 01:54:17
User entered 'No (N)'	System	14 Aug 2020 01:54:17

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-13T20:54:14', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9ef3b1aa-82d6-40f3-a240-5c4a2dda93b7'	System	14 Aug 2020 01:54:17
User entered '13 Aug 2020 20:54'	System	14 Aug 2020 01:54:17

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 20:49'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 2'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-14T14:50:24', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '58a23c2e-0d24-4b08-b5e3-d6f066f9db83'	System	14 Aug 2020 19:51:07
User entered 'None (0)'	System	14 Aug 2020 19:51:07

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-14T14:50:31', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '58a23c2e-0d24-4b08-b5e3-d6f066f9db83'	System	14 Aug 2020 19:51:07
User entered 'None (0)'	System	14 Aug 2020 19:51:07

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-14T14:50:36', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '58a23c2e-0d24-4b08-b5e3-d6f066f9db83'	System	14 Aug 2020 19:51:07
User entered 'None (0)'	System	14 Aug 2020 19:51:07

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-14T14:50:41', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '58a23c2e-0d24-4b08-b5e3-d6f066f9db83'	System	14 Aug 2020 19:51:07
User entered 'None (0)'	System	14 Aug 2020 19:51:07

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-14T14:50:49', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '58a23c2e-0d24-4b08-b5e3-d6f066f9db83'	System	14 Aug 2020 19:51:07
User entered 'None (0)'	System	14 Aug 2020 19:51:07

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-14T14:50:52', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '58a23c2e-0d24-4b08-b5e3-d6f066f9db83'	System	14 Aug 2020 19:51:07
User entered 'None (0)'	System	14 Aug 2020 19:51:07

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-14T14:50:58', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '58a23c2e-0d24-4b08-b5e3-d6f066f9db83'	System	14 Aug 2020 19:51:07
User entered 'No (N)'	System	14 Aug 2020 19:51:07

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-14T14:51:05', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '58a23c2e-0d24-4b08-b5e3-d6f066f9db83'	System	14 Aug 2020 19:51:07
User entered '14 Aug 2020 14:51'	System	14 Aug 2020 19:51:07

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 3'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-15T16:42:03', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '798ef79c-6065-480b-8456-0cd5dd3b12c9'	System	15 Aug 2020 21:42:21
User entered 'No interference with activity (1)'	System	15 Aug 2020 21:42:21

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-15T16:42:05', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '798ef79c-6065-480b-8456-0cd5dd3b12c9'	System	15 Aug 2020 21:42:21
User entered 'None (0)'	System	15 Aug 2020 21:42:21

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-15T16:42:08', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '798ef79c-6065-480b-8456-0cd5dd3b12c9'	System	15 Aug 2020 21:42:21
User entered 'None (0)'	System	15 Aug 2020 21:42:21

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-15T16:42:10', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '798ef79c-6065-480b-8456-0cd5dd3b12c9'	System	15 Aug 2020 21:42:21
User entered 'None (0)'	System	15 Aug 2020 21:42:21

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-15T16:42:12', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '798ef79c-6065-480b-8456-0cd5dd3b12c9'	System	15 Aug 2020 21:42:21
User entered 'None (0)'	System	15 Aug 2020 21:42:21

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-15T16:42:14', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '798ef79c-6065-480b-8456-0cd5dd3b12c9'	System	15 Aug 2020 21:42:21
User entered 'None (0)'	System	15 Aug 2020 21:42:21

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-15T16:42:17', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '798ef79c-6065-480b-8456-0cd5dd3b12c9'	System	15 Aug 2020 21:42:21
User entered 'No (N)'	System	15 Aug 2020 21:42:21

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-15T16:42:19', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '798ef79c-6065-480b-8456-0cd5dd3b12c9'	System	15 Aug 2020 21:42:21
User entered '15 Aug 2020 16:42'	System	15 Aug 2020 21:42:21

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 4'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-16T14:18:30', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e6762b19-5d89-4e17-b432-5038e5caa9e6'	System	16 Aug 2020 19:18:49
User entered 'None (0)'	System	16 Aug 2020 19:18:49

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-16T14:18:33', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e6762b19-5d89-4e17-b432-5038e5caa9e6'	System	16 Aug 2020 19:18:49
User entered 'None (0)'	System	16 Aug 2020 19:18:49

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-16T14:18:36', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e6762b19-5d89-4e17-b432-5038e5caa9e6'	System	16 Aug 2020 19:18:49
User entered 'None (0)'	System	16 Aug 2020 19:18:49

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-16T14:18:38', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e6762b19-5d89-4e17-b432-5038e5caa9e6'	System	16 Aug 2020 19:18:49
User entered 'None (0)'	System	16 Aug 2020 19:18:49

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-16T14:18:40', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e6762b19-5d89-4e17-b432-5038e5caa9e6'	System	16 Aug 2020 19:18:49
User entered 'None (0)'	System	16 Aug 2020 19:18:49

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-16T14:18:42', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e6762b19-5d89-4e17-b432-5038e5caa9e6'	System	16 Aug 2020 19:18:49
User entered 'None (0)'	System	16 Aug 2020 19:18:49

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-16T14:18:45', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e6762b19-5d89-4e17-b432-5038e5caa9e6'	System	16 Aug 2020 19:18:49
User entered 'No (N)'	System	16 Aug 2020 19:18:49

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-16T14:18:47', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e6762b19-5d89-4e17-b432-5038e5caa9e6'	System	16 Aug 2020 19:18:49
User entered '16 Aug 2020 14:18'	System	16 Aug 2020 19:18:49

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 5'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-17T17:33:54', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cb385f7d-b832-4337-b685-99b116853a2d'	System	17 Aug 2020 22:34:16
User entered 'None (0)'	System	17 Aug 2020 22:34:16

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-17T17:33:57', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cb385f7d-b832-4337-b685-99b116853a2d'	System	17 Aug 2020 22:34:16
User entered 'None (0)'	System	17 Aug 2020 22:34:16

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-17T17:33:59', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cb385f7d-b832-4337-b685-99b116853a2d'	System	17 Aug 2020 22:34:16
User entered 'None (0)'	System	17 Aug 2020 22:34:16

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-17T17:34:01', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cb385f7d-b832-4337-b685-99b116853a2d'	System	17 Aug 2020 22:34:16
User entered 'None (0)'	System	17 Aug 2020 22:34:16

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-17T17:34:04', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cb385f7d-b832-4337-b685-99b116853a2d'	System	17 Aug 2020 22:34:16
User entered 'None (0)'	System	17 Aug 2020 22:34:16

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-17T17:34:06', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cb385f7d-b832-4337-b685-99b116853a2d'	System	17 Aug 2020 22:34:16
User entered 'None (0)'	System	17 Aug 2020 22:34:16

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-17T17:34:09', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cb385f7d-b832-4337-b685-99b116853a2d'	System	17 Aug 2020 22:34:16
User entered 'No (N)'	System	17 Aug 2020 22:34:16

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-17T17:34:15', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cb385f7d-b832-4337-b685-99b116853a2d'	System	17 Aug 2020 22:34:16
User entered '17 Aug 2020 17:34'	System	17 Aug 2020 22:34:16

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 6'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T07:11:38', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '42f3781e-b702-470a-b6a0-3512c2aa01c6'	System	19 Aug 2020 12:11:55
User entered 'None (0)'	System	19 Aug 2020 12:11:55

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T07:11:40', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '42f3781e-b702-470a-b6a0-3512c2aa01c6'	System	19 Aug 2020 12:11:55
User entered 'None (0)'	System	19 Aug 2020 12:11:55

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T07:11:41', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '42f3781e-b702-470a-b6a0-3512c2aa01c6'	System	19 Aug 2020 12:11:55
User entered 'None (0)'	System	19 Aug 2020 12:11:55

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T07:11:43', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '42f3781e-b702-470a-b6a0-3512c2aa01c6'	System	19 Aug 2020 12:11:55
User entered 'None (0)'	System	19 Aug 2020 12:11:55

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T07:11:44', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '42f3781e-b702-470a-b6a0-3512c2aa01c6'	System	19 Aug 2020 12:11:55
User entered 'None (0)'	System	19 Aug 2020 12:11:55

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T07:11:46', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '42f3781e-b702-470a-b6a0-3512c2aa01c6'	System	19 Aug 2020 12:11:55
User entered 'None (0)'	System	19 Aug 2020 12:11:55

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T07:11:49', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '42f3781e-b702-470a-b6a0-3512c2aa01c6'	System	19 Aug 2020 12:11:55
User entered 'No (N)'	System	19 Aug 2020 12:11:55

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T07:11:51', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '42f3781e-b702-470a-b6a0-3512c2aa01c6'	System	19 Aug 2020 12:11:55
User entered '19 Aug 2020 07:11'	System	19 Aug 2020 12:11:55

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 7'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T22:05:21', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e2b62216-a46e-40ed-ab8b-8cdc4d4e555d'	System	20 Aug 2020 03:05:48
User entered 'None (0)'	System	20 Aug 2020 03:05:48

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T22:05:24', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e2b62216-a46e-40ed-ab8b-8cdc4d4e555d'	System	20 Aug 2020 03:05:48
User entered 'None (0)'	System	20 Aug 2020 03:05:48

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T22:05:27', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e2b62216-a46e-40ed-ab8b-8cdc4d4e555d'	System	20 Aug 2020 03:05:48
User entered 'None (0)'	System	20 Aug 2020 03:05:48

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T22:05:29', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e2b62216-a46e-40ed-ab8b-8cdc4d4e555d'	System	20 Aug 2020 03:05:48
User entered 'None (0)'	System	20 Aug 2020 03:05:48

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T22:05:31', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e2b62216-a46e-40ed-ab8b-8cdc4d4e555d'	System	20 Aug 2020 03:05:48
User entered 'None (0)'	System	20 Aug 2020 03:05:48

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T22:05:34', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e2b62216-a46e-40ed-ab8b-8cdc4d4e555d'	System	20 Aug 2020 03:05:48
User entered 'None (0)'	System	20 Aug 2020 03:05:48

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T22:05:39', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e2b62216-a46e-40ed-ab8b-8cdc4d4e555d'	System	20 Aug 2020 03:05:48
User entered 'No (N)'	System	20 Aug 2020 03:05:48

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-08-19T22:05:45', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e2b62216-a46e-40ed-ab8b-8cdc4d4e555d'	System	20 Aug 2020 03:05:48
User entered '19 Aug 2020 22:05'	System	20 Aug 2020 03:05:48

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 23:03:14

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	23 Aug 2020 21:45:32

US3252166

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '21 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	23 Aug 2020 21:45:32

US3252166

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[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)	23 Aug 2020 21:45:32

US3252166

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	23 Aug 2020 21:45:32

US3252166

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	23 Aug 2020 21:45:39

US3252166

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Aug 2020 21:45:39

US3252166

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	28 Aug 2020 15:18:33

US3252166

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

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 15:18:33

US3252166

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[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 15:18:33

US3252166

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	28 Aug 2020 15:18:33

US3252166

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[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 15:18:39

US3252166

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Aug 2020 15:18:39

US3252166

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	05 Sep 2020 21:20:36

US3252166

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '5 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	05 Sep 2020 21:20:36

US3252166

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[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)	05 Sep 2020 21:20:36

US3252166

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	05 Sep 2020 21:20:36

US3252166

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	05 Sep 2020 21:20:57

US3252166

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Sep 2020 21:20:57

US3252166

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:06:36

US3252166

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:06:36

US3252166

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

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)	11 Sep 2020 22:06:36

US3252166

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	11 Sep 2020 22:06:36

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '14:23'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 14:23'	System	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '77'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '16'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '118'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '77'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '16:15'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 16:15'	System	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.7' F	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '72'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '15'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '126'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '77'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:15

US3252166

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:08:15

US3252166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 20:58:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 20:58:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	10 Sep 2020 20:58:59
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 20:45:28
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	10 Sep 2020 20:45:28

US3252166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	10 Sep 2020 20:45:28

US3252166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

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)	10 Sep 2020 20:45:28

US3252166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 20:58:59
User entered empty.	System	10 Sep 2020 20:45:28

US3252166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Joanna Gurrola (b) (4) (b) (4)	10 Sep 2020 20:45:28

US3252166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '15:29'	Joanna Gurrola (b) (4) (b) (4)	10 Sep 2020 20:45:28

US3252166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:29'	System	10 Sep 2020 20:45:28

US3252166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola (b) (4) (b) (4)	10 Sep 2020 20:45:28

US3252166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	10 Sep 2020 20:58:59
User entered empty.	System	10 Sep 2020 20:45:28

US3252166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 20:58:59
User entered empty.	System	10 Sep 2020 20:45:28

US3252166

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:09:13

US3252166

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:09:13

US3252166

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '14:32'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:09:13

US3252166

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 14:32'	System	11 Sep 2020 22:09:13

US3252166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:51:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:09:33

US3252166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:06

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:09:33

US3252166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:09:33

US3252166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '14:28'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:09:33

US3252166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 14:28'	System	11 Sep 2020 22:09:33

US3252166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:06

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:09:33

US3252166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:09:33

US3252166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:09:33

US3252166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 22:09:33

US3252166

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 22:09:43

US3252166

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 22:09:43

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T16:16:11', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8cfb8e77-aff9-42b8-bdc6-0f8d38575445'	System	10 Sep 2020 21:16:28
User entered 'Yes (Y)'	System	10 Sep 2020 21:16:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T16:16:15', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8cfb8e77-aff9-42b8-bdc6-0f8d38575445'	System	10 Sep 2020 21:16:28
User entered '97.7'	System	10 Sep 2020 21:16:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T16:16:19', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8cfb8e77-aff9-42b8-bdc6-0f8d38575445'	System	10 Sep 2020 21:16:28
User entered 'No (N)'	System	10 Sep 2020 21:16:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T16:16:25', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8cfb8e77-aff9-42b8-bdc6-0f8d38575445'	System	10 Sep 2020 21:16:28
User entered '10 Sep 2020 16:16'	System	10 Sep 2020 21:16:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:49'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 18:19'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T19:14:18', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'aaf67962-3b87-47b0-9dbc-00ea5bc2a33c'	System	11 Sep 2020 00:15:33
User entered 'Yes (Y)'	System	11 Sep 2020 00:15:33

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T19:15:08', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'aaf67962-3b87-47b0-9dbc-00ea5bc2a33c'	System	11 Sep 2020 00:15:33
User entered '96.0'	System	11 Sep 2020 00:15:33

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T19:15:12', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'aaf67962-3b87-47b0-9dbc-00ea5bc2a33c'	System	11 Sep 2020 00:15:33
User entered 'No (N)'	System	11 Sep 2020 00:15:33

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T19:15:30', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'aaf67962-3b87-47b0-9dbc-00ea5bc2a33c'	System	11 Sep 2020 00:15:33
User entered '10 Sep 2020 19:15'	System	11 Sep 2020 00:15:33

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 19:14'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 2'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-11T15:46:21', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'afb6035a-49fb-474e-a24d-88562cf0f080'	System	11 Sep 2020 20:46:39
User entered 'Yes (Y)'	System	11 Sep 2020 20:46:39

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-11T15:46:26', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'afb6035a-49fb-474e-a24d-88562cf0f080'	System	11 Sep 2020 20:46:39
User entered '97.5'	System	11 Sep 2020 20:46:39

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-11T15:46:30', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'afb6035a-49fb-474e-a24d-88562cf0f080'	System	11 Sep 2020 20:46:39
User entered 'No (N)'	System	11 Sep 2020 20:46:39

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-11T15:46:34', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'afb6035a-49fb-474e-a24d-88562cf0f080'	System	11 Sep 2020 20:46:39
User entered '11 Sep 2020 15:46'	System	11 Sep 2020 20:46:39

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 3'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-12T12:00:41', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '6d2122b8-4f5a-42d3-aaab-45bb0ca02bc3'	System	12 Sep 2020 17:01:57
User entered 'Yes (Y)'	System	12 Sep 2020 17:01:57

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-12T12:00:45', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '6d2122b8-4f5a-42d3-aaab-45bb0ca02bc3' User entered '97.5'	System	12 Sep 2020 17:01:57
	System	12 Sep 2020 17:01:57

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-12T12:00:51', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '6d2122b8-4f5a-42d3-aaab-45bb0ca02bc3'	System	12 Sep 2020 17:01:57
User entered 'Yes (Y)'	System	12 Sep 2020 17:01:57

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient was contacted and confirmed that they took medication. It has been added to the conmeds.' (Site from System).	(b) (4), (b) (6)	31 Oct 2020 17:05:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-12T12:01:12', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '6d2122b8-4f5a-42d3-aaab-45bb0ca02bc3'	System	12 Sep 2020 17:01:57
User entered '1'	System	12 Sep 2020 17:01:57

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:06

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-12T12:01:12', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '6d2122b8-4f5a-42d3-aaab-45bb0ca02bc3' User entered '0'	System	12 Sep 2020 17:01:57
	System	12 Sep 2020 17:01:57

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-12T12:01:18', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '6d2122b8-4f5a-42d3-aaab-45bb0ca02bc3'	System	12 Sep 2020 17:01:57
User entered '12 Sep 2020 12:01'	System	12 Sep 2020 17:01:57

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 4'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-13T20:36:11', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '752408f5-a328-4ad7-b82a-ed5764207ebf'	System	14 Sep 2020 01:36:27
User entered 'Yes (Y)'	System	14 Sep 2020 01:36:27

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-13T20:36:18', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '752408f5-a328-4ad7-b82a-ed5764207ebf'	System	14 Sep 2020 01:36:27
User entered '94.6'	System	14 Sep 2020 01:36:27

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-13T20:36:21', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '752408f5-a328-4ad7-b82a-ed5764207ebf'	System	14 Sep 2020 01:36:27
User entered 'No (N)'	System	14 Sep 2020 01:36:27

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-13T20:36:24', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '752408f5-a328-4ad7-b82a-ed5764207ebf'	System	14 Sep 2020 01:36:27
User entered '13 Sep 2020 20:36'	System	14 Sep 2020 01:36:27

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 5'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-14T21:04:20', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '59c5c362-c502-4645-80df-804c007905fe' User entered 'Yes (Y)'	System	15 Sep 2020 02:05:21
	System	15 Sep 2020 02:05:21

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-14T21:04:26', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '59c5c362-c502-4645-80df-804c007905fe' User entered '96.5'	System	15 Sep 2020 02:05:21

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-14T21:05:11', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '59c5c362-c502-4645-80df-804c007905fe' User entered 'No (N)'	System	15 Sep 2020 02:05:21
	System	15 Sep 2020 02:05:21

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-14T21:05:18', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '59c5c362-c502-4645-80df-804c007905fe' User entered '14 Sep 2020 21:05'	System	15 Sep 2020 02:05:21
	System	15 Sep 2020 02:05:21

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 6'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-15T19:39:59', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '341db433-54bb-470a-b5de-d62d9c646f79'	System	16 Sep 2020 00:40:30
User entered 'Yes (Y)'	System	16 Sep 2020 00:40:30

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-15T19:40:20', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '341db433-54bb-470a-b5de-d62d9c646f79'	System	16 Sep 2020 00:40:30
User entered '96.5'	System	16 Sep 2020 00:40:30

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-15T19:40:22', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '341db433-54bb-470a-b5de-d62d9c646f79'	System	16 Sep 2020 00:40:30
User entered 'No (N)'	System	16 Sep 2020 00:40:30

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-15T19:40:27', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '341db433-54bb-470a-b5de-d62d9c646f79'	System	16 Sep 2020 00:40:30
User entered '15 Sep 2020 19:40'	System	16 Sep 2020 00:40:30

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 7'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-16T20:52:01', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'f2d3f292-2e8f-44da-b801-d036efc47fc8'	System	17 Sep 2020 01:52:16
User entered 'Yes (Y)'	System	17 Sep 2020 01:52:16

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-16T20:52:05', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'f2d3f292-2e8f-44da-b801-d036efc47fc8'	System	17 Sep 2020 01:52:16
User entered '97.2'	System	17 Sep 2020 01:52:16

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-16T20:52:09', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'f2d3f292-2e8f-44da-b801-d036efc47fc8'	System	17 Sep 2020 01:52:16
User entered 'No (N)'	System	17 Sep 2020 01:52:16

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-16T20:52:12', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'f2d3f292-2e8f-44da-b801-d036efc47fc8'	System	17 Sep 2020 01:52:16
User entered '16 Sep 2020 20:52'	System	17 Sep 2020 01:52:16

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T16:16:30', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '668e55d8-b54e-4859-83d8-d61f90030e52'	System	10 Sep 2020 21:16:45
User entered 'None (1)'	System	10 Sep 2020 21:16:45

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T16:16:34', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '668e55d8-b54e-4859-83d8-d61f90030e52'	System	10 Sep 2020 21:16:45
User entered 'No (N)'	System	10 Sep 2020 21:16:45

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T16:16:37', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '668e55d8-b54e-4859-83d8-d61f90030e52'	System	10 Sep 2020 21:16:45
User entered 'No (N)'	System	10 Sep 2020 21:16:45

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T16:16:40', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '668e55d8-b54e-4859-83d8-d61f90030e52'	System	10 Sep 2020 21:16:45
User entered 'None (1)'	System	10 Sep 2020 21:16:45

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T16:16:42', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '668e55d8-b54e-4859-83d8-d61f90030e52'	System	10 Sep 2020 21:16:45
User entered '10 Sep 2020 16:16'	System	10 Sep 2020 21:16:45

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:49'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 18:19'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T19:15:36', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8101b757-6fa0-4f3d-9369-23e33a82f07e'	System	11 Sep 2020 00:16:53
User entered 'None (1)'	System	11 Sep 2020 00:16:53

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T19:15:41', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8101b757-6fa0-4f3d-9369-23e33a82f07e'	System	11 Sep 2020 00:16:53
User entered 'No (N)'	System	11 Sep 2020 00:16:53

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T19:15:45', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8101b757-6fa0-4f3d-9369-23e33a82f07e'	System	11 Sep 2020 00:16:53
User entered 'No (N)'	System	11 Sep 2020 00:16:53

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T19:16:02', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8101b757-6fa0-4f3d-9369-23e33a82f07e'	System	11 Sep 2020 00:16:53
User entered 'None (1)'	System	11 Sep 2020 00:16:53

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T19:16:51', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8101b757-6fa0-4f3d-9369-23e33a82f07e'	System	11 Sep 2020 00:16:53
User entered '10 Sep 2020 19:16'	System	11 Sep 2020 00:16:53

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 19:14'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 2'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-11T15:46:48', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'b7839746-9ba2-4625-b399-24bc0f84c83d'	System	11 Sep 2020 20:47:23
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 20:47:23

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-11T15:46:51', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'b7839746-9ba2-4625-b399-24bc0f84c83d'	System	11 Sep 2020 20:47:23
User entered 'No (N)'	System	11 Sep 2020 20:47:23

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-11T15:46:55', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'b7839746-9ba2-4625-b399-24bc0f84c83d'	System	11 Sep 2020 20:47:23
User entered 'No (N)'	System	11 Sep 2020 20:47:23

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-11T15:47:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'b7839746-9ba2-4625-b399-24bc0f84c83d'	System	11 Sep 2020 20:47:23
User entered 'None (1)'	System	11 Sep 2020 20:47:23

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-11T15:47:04', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'b7839746-9ba2-4625-b399-24bc0f84c83d'	System	11 Sep 2020 20:47:23
User entered '11 Sep 2020 15:47'	System	11 Sep 2020 20:47:23

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 3'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:06

[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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-12T12:01:25', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '38736179-329e-459f-8b1f-dab153368ab0'	System	12 Sep 2020 17:02:32
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 17:02:32

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-12T12:01:30', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '38736179-329e-459f-8b1f-dab153368ab0'	System	12 Sep 2020 17:02:32
User entered 'No (N)'	System	12 Sep 2020 17:02:32

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-12T12:01:33', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '38736179-329e-459f-8b1f-dab153368ab0'	System	12 Sep 2020 17:02:32
User entered 'No (N)'	System	12 Sep 2020 17:02:32

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-12T12:01:37', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '38736179-329e-459f-8b1f-dab153368ab0' User entered 'None (1)'	System	12 Sep 2020 17:02:32
	System	12 Sep 2020 17:02:32

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-12T12:01:44', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '38736179-329e-459f-8b1f-dab153368ab0' User entered '12 Sep 2020 12:01'	System	12 Sep 2020 17:02:32
	System	12 Sep 2020 17:02:32

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 4'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-13T20:36:28', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '25292bbb-90e3-4b15-94f5-6cc3f68448d9' User entered 'None (1)'	System	14 Sep 2020 01:36:39
	System	14 Sep 2020 01:36:39

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-13T20:36:30', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '25292bbb-90e3-4b15-94f5-6cc3f68448d9'	System	14 Sep 2020 01:36:39
User entered 'No (N)'	System	14 Sep 2020 01:36:39

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-13T20:36:33', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '25292bbb-90e3-4b15-94f5-6cc3f68448d9' User entered 'No (N)'	System	14 Sep 2020 01:36:39

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-13T20:36:35', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '25292bbb-90e3-4b15-94f5-6cc3f68448d9' User entered 'None (1)'	System	14 Sep 2020 01:36:39
	System	14 Sep 2020 01:36:39

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-13T20:36:38', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '25292bbb-90e3-4b15-94f5-6cc3f68448d9' User entered '13 Sep 2020 20:36'	System	14 Sep 2020 01:36:39
	System	14 Sep 2020 01:36:39

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 5'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:06

[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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-14T21:05:25', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '2f6ec8f3-5a71-4f3c-a9c3-712320fec4ce' User entered 'None (1)'	System	15 Sep 2020 02:05:41
	System	15 Sep 2020 02:05:41

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-14T21:05:28', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '2f6ec8f3-5a71-4f3c-a9c3-712320fec4ce'	System	15 Sep 2020 02:05:41
User entered 'No (N)'	System	15 Sep 2020 02:05:41

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-14T21:05:31', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '2f6ec8f3-5a71-4f3c-a9c3-712320fec4ce'	System	15 Sep 2020 02:05:41
User entered 'No (N)'	System	15 Sep 2020 02:05:41

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-14T21:05:33', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '2f6ec8f3-5a71-4f3c-a9c3-712320fec4ce' User entered 'None (1)'	System	15 Sep 2020 02:05:41
	System	15 Sep 2020 02:05:41

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-14T21:05:36', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '2f6ec8f3-5a71-4f3c-a9c3-712320fec4ce'	System	15 Sep 2020 02:05:41
User entered '14 Sep 2020 21:05'	System	15 Sep 2020 02:05:41

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 6'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-15T19:40:32', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9f3cca08-3b40-4072-b9fb-baf6f99885de'	System	16 Sep 2020 00:40:59
User entered 'None (1)'	System	16 Sep 2020 00:40:59

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-15T19:40:35', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9f3cca08-3b40-4072-b9fb-baf6f99885de'	System	16 Sep 2020 00:40:59
User entered 'No (N)'	System	16 Sep 2020 00:40:59

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-15T19:40:40', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9f3cca08-3b40-4072-b9fb-baf6f99885de'	System	16 Sep 2020 00:40:59
User entered 'No (N)'	System	16 Sep 2020 00:40:59

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-15T19:40:46', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9f3cca08-3b40-4072-b9fb-baf6f99885de' User entered 'None (1)'	System	16 Sep 2020 00:40:59
	System	16 Sep 2020 00:40:59

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-15T19:40:57', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9f3cca08-3b40-4072-b9fb-baf6f99885de' User entered '15 Sep 2020 19:40'	System	16 Sep 2020 00:40:59
	System	16 Sep 2020 00:40:59

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 7'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:06

[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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-16T20:52:16', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'd7bd36e2-1b00-434f-aaa8-a8073007b04a'	System	17 Sep 2020 01:52:34
User entered 'None (1)'	System	17 Sep 2020 01:52:34

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-16T20:52:19', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'd7bd36e2-1b00-434f-aaa8-a8073007b04a'	System	17 Sep 2020 01:52:34
User entered 'No (N)'	System	17 Sep 2020 01:52:34

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-16T20:52:21', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'd7bd36e2-1b00-434f-aaa8-a8073007b04a'	System	17 Sep 2020 01:52:34
User entered 'No (N)'	System	17 Sep 2020 01:52:34

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-16T20:52:25', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'd7bd36e2-1b00-434f-aaa8-a8073007b04a'	System	17 Sep 2020 01:52:34
User entered 'None (1)'	System	17 Sep 2020 01:52:34

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-16T20:52:31', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'd7bd36e2-1b00-434f-aaa8-a8073007b04a'	System	17 Sep 2020 01:52:34
User entered '16 Sep 2020 20:52'	System	17 Sep 2020 01:52:34

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T16:16:47', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cfcf00ee-9a97-4da8-88af-6596b41a7d78'	System	10 Sep 2020 22:39:47
User entered 'None (0)'	System	10 Sep 2020 22:39:47

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T16:16:49', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cfcf00ee-9a97-4da8-88af-6596b41a7d78'	System	10 Sep 2020 22:39:47
User entered 'None (0)'	System	10 Sep 2020 22:39:47

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T16:16:52', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cfcf00ee-9a97-4da8-88af-6596b41a7d78'	System	10 Sep 2020 22:39:47
User entered 'None (0)'	System	10 Sep 2020 22:39:47

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T16:16:55', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cfcf00ee-9a97-4da8-88af-6596b41a7d78'	System	10 Sep 2020 22:39:47
User entered 'None (0)'	System	10 Sep 2020 22:39:47

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T16:16:57', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cfcf00ee-9a97-4da8-88af-6596b41a7d78'	System	10 Sep 2020 22:39:47
User entered 'None (0)'	System	10 Sep 2020 22:39:47

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T16:16:59', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cfcf00ee-9a97-4da8-88af-6596b41a7d78'	System	10 Sep 2020 22:39:47
User entered 'None (0)'	System	10 Sep 2020 22:39:47

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T16:17:05', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cfcf00ee-9a97-4da8-88af-6596b41a7d78'	System	10 Sep 2020 22:39:47
User entered 'No (N)'	System	10 Sep 2020 22:39:47

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T16:17:08', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'cfcf00ee-9a97-4da8-88af-6596b41a7d78'	System	10 Sep 2020 22:39:47
User entered '10 Sep 2020 16:17'	System	10 Sep 2020 22:39:47

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:49'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 18:19'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T19:16:55', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a9b9ffaa-5fb6-4bb4-bbe9-e0e791b93ffa'	System	11 Sep 2020 00:17:21
User entered 'None (0)'	System	11 Sep 2020 00:17:21

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T19:16:58', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a9b9ffaa-5fb6-4bb4-bbe9-e0e791b93ffa'	System	11 Sep 2020 00:17:21
User entered 'None (0)'	System	11 Sep 2020 00:17:21

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T19:17:01', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a9b9ffaa-5fb6-4bb4-bbe9-e0e791b93ffa' User entered 'None (0)'	System	11 Sep 2020 00:17:21
	System	11 Sep 2020 00:17:21

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T19:17:06', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a9b9ffaa-5fb6-4bb4-bbe9-e0e791b93ffa' User entered 'None (0)'	System	11 Sep 2020 00:17:21

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T19:17:08', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a9b9ffaa-5fb6-4bb4-bbe9-e0e791b93ffa'	System	11 Sep 2020 00:17:21
User entered 'None (0)'	System	11 Sep 2020 00:17:21

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T19:17:12', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a9b9ffaa-5fb6-4bb4-bbe9-e0e791b93ffa'	System	11 Sep 2020 00:17:21
User entered 'None (0)'	System	11 Sep 2020 00:17:21

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T19:17:15', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a9b9ffaa-5fb6-4bb4-bbe9-e0e791b93ffa'	System	11 Sep 2020 00:17:21
User entered 'No (N)'	System	11 Sep 2020 00:17:21

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-10T19:17:19', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a9b9ffaa-5fb6-4bb4-bbe9-e0e791b93ffa' User entered '10 Sep 2020 19:17'	System	11 Sep 2020 00:17:21
	System	11 Sep 2020 00:17:21

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 19:14'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 2'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-11T15:47:11', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '50d3dffc-cc2d-4014-bf43-889394efe1b1'	System	11 Sep 2020 20:48:03
User entered 'No interference with activity (1)'	System	11 Sep 2020 20:48:03

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-11T15:47:26', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '50d3dffc-cc2d-4014-bf43-889394efe1b1'	System	11 Sep 2020 20:48:03
User entered 'No interference with activity (1)'	System	11 Sep 2020 20:48:03

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-11T15:47:35', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '50d3dffc-cc2d-4014-bf43-889394efe1b1'	System	11 Sep 2020 20:48:03
User entered 'Some interference with activity (2)'	System	11 Sep 2020 20:48:03

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-11T15:47:42', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '50d3dffc-cc2d-4014-bf43-889394efe1b1'	System	11 Sep 2020 20:48:03
User entered 'Some interference with activity (2)'	System	11 Sep 2020 20:48:03

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-11T15:47:45', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '50d3dffc-cc2d-4014-bf43-889394efe1b1'	System	11 Sep 2020 20:48:03
User entered 'None (0)'	System	11 Sep 2020 20:48:03

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-11T15:47:48', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '50d3dffc-cc2d-4014-bf43-889394efe1b1'	System	11 Sep 2020 20:48:03
User entered 'None (0)'	System	11 Sep 2020 20:48:03

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-11T15:47:54', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '50d3dffc-cc2d-4014-bf43-889394efe1b1' User entered 'No (N)'	System	11 Sep 2020 20:48:03

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-11T15:47:58', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '50d3dffc-cc2d-4014-bf43-889394efe1b1'	System	11 Sep 2020 20:48:03
User entered '11 Sep 2020 15:47'	System	11 Sep 2020 20:48:03

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 3'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-12T12:01:52', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'bbe978dd-f359-4282-8ffb-bb5b5927d958'	System	12 Sep 2020 17:03:17
User entered 'None (0)'	System	12 Sep 2020 17:03:17

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-12T12:02:02', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'bbe978dd-f359-4282-8ffb-bb5b5927d958'	System	12 Sep 2020 17:03:17
User entered 'None (0)'	System	12 Sep 2020 17:03:17

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-12T12:02:10', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'bbe978dd-f359-4282-8ffb-bb5b5927d958'	System	12 Sep 2020 17:03:17
User entered 'No interference with activity (1)'	System	12 Sep 2020 17:03:17

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-12T12:02:20', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'bbe978dd-f359-4282-8ffb-bb5b5927d958'	System	12 Sep 2020 17:03:17
User entered 'No interference with activity (1)'	System	12 Sep 2020 17:03:17

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-12T12:02:22', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'bbe978dd-f359-4282-8ffb-bb5b5927d958'	System	12 Sep 2020 17:03:17
User entered 'None (0)'	System	12 Sep 2020 17:03:17

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-12T12:02:26', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'bbe978dd-f359-4282-8ffb-bb5b5927d958'	System	12 Sep 2020 17:03:17
User entered 'None (0)'	System	12 Sep 2020 17:03:17

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-12T12:02:31', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'bbe978dd-f359-4282-8ffb-bb5b5927d958'	System	12 Sep 2020 17:03:17
User entered 'No (N)'	System	12 Sep 2020 17:03:17

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-12T12:02:35', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'bbe978dd-f359-4282-8ffb-bb5b5927d958'	System	12 Sep 2020 17:03:17
User entered '12 Sep 2020 12:02'	System	12 Sep 2020 17:03:17

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 4'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-13T20:36:41', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'c8c42c82-4668-4073-9c93-ef65cbf8a732'	System	14 Sep 2020 01:37:07
User entered 'None (0)'	System	14 Sep 2020 01:37:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-13T20:36:45', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'c8c42c82-4668-4073-9c93-ef65cbf8a732'	System	14 Sep 2020 01:37:07
User entered 'None (0)'	System	14 Sep 2020 01:37:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-13T20:36:47', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'c8c42c82-4668-4073-9c93-ef65cbf8a732'	System	14 Sep 2020 01:37:07
User entered 'None (0)'	System	14 Sep 2020 01:37:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-13T20:36:51', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'c8c42c82-4668-4073-9c93-ef65cbf8a732'	System	14 Sep 2020 01:37:07
User entered 'None (0)'	System	14 Sep 2020 01:37:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-13T20:36:53', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'c8c42c82-4668-4073-9c93-ef65cbf8a732'	System	14 Sep 2020 01:37:07
User entered 'None (0)'	System	14 Sep 2020 01:37:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-13T20:36:57', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'c8c42c82-4668-4073-9c93-ef65cbf8a732'	System	14 Sep 2020 01:37:07
User entered 'None (0)'	System	14 Sep 2020 01:37:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-13T20:37:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'c8c42c82-4668-4073-9c93-ef65cbf8a732'	System	14 Sep 2020 01:37:07
User entered 'No (N)'	System	14 Sep 2020 01:37:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-13T20:37:05', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'c8c42c82-4668-4073-9c93-ef65cbf8a732'	System	14 Sep 2020 01:37:07
User entered '13 Sep 2020 20:37'	System	14 Sep 2020 01:37:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 5'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-14T21:05:39', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '43c60096-ae8e-4245-a55e-8f6feeefdb5'	System	15 Sep 2020 02:06:04
User entered 'None (0)'	System	15 Sep 2020 02:06:04

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-14T21:05:42', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '43c60096-ae8e-4245-a55e-8f6feeefdb5'	System	15 Sep 2020 02:06:04
User entered 'None (0)'	System	15 Sep 2020 02:06:04

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-14T21:05:46', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '43c60096-ae8e-4245-a55e-8f6feeefdb5'	System	15 Sep 2020 02:06:04
User entered 'None (0)'	System	15 Sep 2020 02:06:04

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-14T21:05:49', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '43c60096-ae8e-4245-a55e-8f6feefdba5'	System	15 Sep 2020 02:06:04
User entered 'None (0)'	System	15 Sep 2020 02:06:04

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-14T21:05:51', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '43c60096-ae8e-4245-a55e-8f6feeefdb5'	System	15 Sep 2020 02:06:04
User entered 'None (0)'	System	15 Sep 2020 02:06:04

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-14T21:05:53', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '43c60096-ae8e-4245-a55e-8f6feeefdb5'	System	15 Sep 2020 02:06:04
User entered 'None (0)'	System	15 Sep 2020 02:06:04

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-14T21:05:56', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '43c60096-ae8e-4245-a55e-8f6feeefdb5'	System	15 Sep 2020 02:06:04
User entered 'No (N)'	System	15 Sep 2020 02:06:04

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-14T21:06:02', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '43c60096-ae8e-4245-a55e-8f6feeefdb5'	System	15 Sep 2020 02:06:04
User entered '14 Sep 2020 21:06'	System	15 Sep 2020 02:06:04

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 6'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-15T19:41:04', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e291ff2e-932f-441b-bc7b-b24d1f60709c'	System	16 Sep 2020 00:41:31
User entered 'None (0)'	System	16 Sep 2020 00:41:31

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-15T19:41:07', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e291ff2e-932f-441b-bc7b-b24d1f60709c'	System	16 Sep 2020 00:41:31
User entered 'None (0)'	System	16 Sep 2020 00:41:31

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-15T19:41:10', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e291ff2e-932f-441b-bc7b-b24d1f60709c'	System	16 Sep 2020 00:41:31
User entered 'None (0)'	System	16 Sep 2020 00:41:31

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-15T19:41:14', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e291ff2e-932f-441b-bc7b-b24d1f60709c'	System	16 Sep 2020 00:41:31
User entered 'None (0)'	System	16 Sep 2020 00:41:31

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-15T19:41:16', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e291ff2e-932f-441b-bc7b-b24d1f60709c'	System	16 Sep 2020 00:41:31
User entered 'None (0)'	System	16 Sep 2020 00:41:31

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-15T19:41:18', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e291ff2e-932f-441b-bc7b-b24d1f60709c'	System	16 Sep 2020 00:41:31
User entered 'None (0)'	System	16 Sep 2020 00:41:31

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-15T19:41:22', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e291ff2e-932f-441b-bc7b-b24d1f60709c'	System	16 Sep 2020 00:41:31
User entered 'No (N)'	System	16 Sep 2020 00:41:31

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-15T19:41:26', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'e291ff2e-932f-441b-bc7b-b24d1f60709c'	System	16 Sep 2020 00:41:31
User entered '15 Sep 2020 19:41'	System	16 Sep 2020 00:41:31

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:45:28
User entered 'Day 7'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-16T20:52:35', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'f311e771-e53e-42d9-b1df-d909ebc44bc8' User entered 'None (0)'	System	17 Sep 2020 01:53:07
	System	17 Sep 2020 01:53:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-16T20:52:38', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'f311e771-e53e-42d9-b1df-d909ebc44bc8' User entered 'None (0)'	System	17 Sep 2020 01:53:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-16T20:52:41', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'f311e771-e53e-42d9-b1df-d909ebc44bc8' User entered 'None (0)'	System	17 Sep 2020 01:53:07
	System	17 Sep 2020 01:53:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-16T20:52:44', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'f311e771-e53e-42d9-b1df-d909ebc44bc8'	System	17 Sep 2020 01:53:07
User entered 'None (0)'	System	17 Sep 2020 01:53:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-16T20:52:47', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'f311e771-e53e-42d9-b1df-d909ebc44bc8'	System	17 Sep 2020 01:53:07
User entered 'None (0)'	System	17 Sep 2020 01:53:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-16T20:52:49', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'f311e771-e53e-42d9-b1df-d909ebc44bc8' User entered 'None (0)'	System	17 Sep 2020 01:53:07
	System	17 Sep 2020 01:53:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-16T20:52:58', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'f311e771-e53e-42d9-b1df-d909ebc44bc8'	System	17 Sep 2020 01:53:07
User entered 'No (N)'	System	17 Sep 2020 01:53:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-09-16T20:53:04', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'f311e771-e53e-42d9-b1df-d909ebc44bc8'	System	17 Sep 2020 01:53:07
User entered '16 Sep 2020 20:53'	System	17 Sep 2020 01:53:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:45:28

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:51:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:45:28

US3252166

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	18 Sep 2020 03:34:54

US3252166

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	18 Sep 2020 03:34:54

US3252166

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[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)	18 Sep 2020 03:34:54

US3252166

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	18 Sep 2020 03:34:54

US3252166

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	18 Sep 2020 03:34:59

US3252166

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Sep 2020 03:34:59

US3252166

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 01:47:36

US3252166

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 01:47:36

US3252166

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[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)	25 Sep 2020 01:47:36

US3252166

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 01:47:36

US3252166

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	25 Sep 2020 01:47:39

US3252166

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Sep 2020 01:47:39

US3252166

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	02 Oct 2020 03:24:12

US3252166

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '1 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	02 Oct 2020 03:24:12

US3252166

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[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)	02 Oct 2020 03:24:12

US3252166

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	02 Oct 2020 03:24:12

US3252166

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	02 Oct 2020 03:24:16

US3252166

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Oct 2020 03:24:16

US3252166

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 22:30:52

US3252166

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 22:30:52

US3252166

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Oct 2020 22:30:52

US3252166

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	12 Oct 2020 22:30:52

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 22:31:21

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 22:31:21

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '09:33'	(b) (4), (b) (6)	12 Oct 2020 22:31:21

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '10 Oct 2020 09:33'	System	12 Oct 2020 22:31:21

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.5' F	(b) (4), (b) (6)	12 Oct 2020 22:31:21

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Oct 2020 22:31:21

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:31:21

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '73'	(b) (4), (b) (6)	12 Oct 2020 22:31:21

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Oct 2020 22:31:21

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	12 Oct 2020 22:31:21

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Oct 2020 22:31:21

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '136'	(b) (4), (b) (6)	12 Oct 2020 22:31:21

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 22:31:21

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '82'	(b) (4), (b) (6)	12 Oct 2020 22:31:21

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 22:31:21

US3252166

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 22:31:34

US3252166

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:31:34

US3252166

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 22:31:49

US3252166

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 22:31:49

US3252166

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '09:54'	(b) (4), (b) (6)	12 Oct 2020 22:31:49

US3252166

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '10 Oct 2020 09:54'	System	12 Oct 2020 22:31:49

US3252166

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 22:31:54

US3252166

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 22:31:54

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 64'	System	13 Aug 2020 23:03:14

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-10-13T00:02:05', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8ac2a513-3153-4400-8cd0-433352c0ac93'	System	13 Oct 2020 05:02:46
User entered 'Yes (Y)'	System	13 Oct 2020 05:02:46

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

Have you been exposed to someone with 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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-10-13T00:02:11', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8ac2a513-3153-4400-8cd0-433352c0ac93'	System	13 Oct 2020 05:02:46
User entered 'No (N)'	System	13 Oct 2020 05:02:46

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-10-13T00:02:23', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8ac2a513-3153-4400-8cd0-433352c0ac93'	System	13 Oct 2020 05:02:46
User entered 'No (N)'	System	13 Oct 2020 05:02:46

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-10-13T00:02:33', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8ac2a513-3153-4400-8cd0-433352c0ac93'	System	13 Oct 2020 05:02:46
User entered 'No (N)'	System	13 Oct 2020 05:02:46

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-10-13T00:02:44', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8ac2a513-3153-4400-8cd0-433352c0ac93' User entered '13 Oct 2020 00:02:44'	System	13 Oct 2020 05:02:46
	System	13 Oct 2020 05:02:46

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 23:03:14

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 71'	System	13 Aug 2020 23:03:14

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-10-21T08:22:40', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '840646c4-3a34-4564-85e1-2af3e2a2f57a' User entered 'No (N)'	System	21 Oct 2020 13:22:51
	System	21 Oct 2020 13:22:51

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

Have you been exposed to someone with 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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-10-21T08:22:46', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '840646c4-3a34-4564-85e1-2af3e2a2f57a' User entered 'No (N)'	System	21 Oct 2020 13:22:51
	System	21 Oct 2020 13:22:51

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-10-21T08:22:49', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '840646c4-3a34-4564-85e1-2af3e2a2f57a' User entered '21 Oct 2020 08:22:49'	System	21 Oct 2020 13:22:51
	System	21 Oct 2020 13:22:51

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 23:03:14

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 78'	System	13 Aug 2020 23:03:14

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-10-27T06:10:07', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '383bf200-55db-4b63-9e1d-a686c2d53d1f' User entered 'No (N)'	System	27 Oct 2020 11:10:25
	System	27 Oct 2020 11:10:25

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

Have you been exposed to someone with 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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-10-27T06:10:17', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '383bf200-55db-4b63-9e1d-a686c2d53d1f' User entered 'No (N)'	System	27 Oct 2020 11:10:25
	System	27 Oct 2020 11:10:25

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-10-27T06:10:22', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '383bf200-55db-4b63-9e1d-a686c2d53d1f' User entered '27 Oct 2020 06:10:22'	System	27 Oct 2020 11:10:25
	System	27 Oct 2020 11:10:25

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 23:03:14

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 92'	System	13 Aug 2020 23:03:14

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-11-12T21:53:39', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '367973b6-495e-4f3e-b57f-e0d93dd26536' User entered 'No (N)'	System	13 Nov 2020 04:36:24
	System	13 Nov 2020 04:36:24

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

Have you been exposed to someone with 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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-11-12T22:36:14', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '367973b6-495e-4f3e-b57f-e0d93dd26536' User entered 'No (N)'	System	13 Nov 2020 04:36:24
	System	13 Nov 2020 04:36:24

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-11-12T22:36:22', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '367973b6-495e-4f3e-b57f-e0d93dd26536' User entered '12 Nov 2020 22:36:22'	System	13 Nov 2020 04:36:24
	System	13 Nov 2020 04:36:24

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 23:03:14

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered 'Day 99'	System	13 Aug 2020 23:03:14

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-11-17T07:02:54', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9cee956d-ac04-4bdb-8809-b18fa83f870c'	System	17 Nov 2020 13:03:08
User entered 'No (N)'	System	17 Nov 2020 13:03:08

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

Have you been exposed to someone with 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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-11-17T07:02:59', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9cee956d-ac04-4bdb-8809-b18fa83f870c' User entered 'No (N)'	System	17 Nov 2020 13:03:08

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-11-17T07:03:05', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9cee956d-ac04-4bdb-8809-b18fa83f870c' User entered '17 Nov 2020 07:03:05'	System	17 Nov 2020 13:03:08
	System	17 Nov 2020 13:03:08

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 23:03:14

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:03:14
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 23:03:14

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '10 Oct 2020 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '14 Oct 2020 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '17 Oct 2020 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '21 Oct 2020 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '24 Oct 2020 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '28 Oct 2020 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '31 Oct 2020 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '04 Nov 2020 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '07 Nov 2020 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '11 Nov 2020 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '14 Nov 2020 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '18 Nov 2020 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-11-24T20:27:27', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '0a145dc0-4376-422d-a59b-e6b0644260dd' User entered 'No (N)'	System	25 Nov 2020 02:27:41

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

Have you been exposed to someone with 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 (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-11-24T20:27:30', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '0a145dc0-4376-422d-a59b-e6b0644260dd' User entered 'No (N)'	System	25 Nov 2020 02:27:41

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2020-11-24T20:27:38', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '0a145dc0-4376-422d-a59b-e6b0644260dd' User entered '24 Nov 2020 20:27:38'	System	25 Nov 2020 02:27:41

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:53:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:53:13
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:53:13

US3252166

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	06 Nov 2020 06:12:03

US3252166

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '5 Nov 2020'	Nancy Torrence (b) (4) (b) (4)	06 Nov 2020 06:12:03

US3252166

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[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)	06 Nov 2020 06:12:03

US3252166

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	06 Nov 2020 06:12:03

US3252166

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	06 Nov 2020 06:12:07

US3252166

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 06:12:07

US3252166

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:51:06

[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)	05 Nov 2020 23:12:39
User entered 'No (N)'	Shannon Moyer (b) (4)	14 Aug 2020 20:22:15

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:27:32
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:11
User entered 'USA-US108-2020-mRNA-1273-P301000015'	System	06 Nov 2020 22:30:55
User entered 'New'	(b) (4), (b) (6)	06 Nov 2020 22:30:55

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Thyroid disorder, LLT: Thyroid disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:16:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:16:35
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 18:57:09
Query 'PV Query: Please consider updating the event term to the condition for which the surgery was performed. If the condition was part of the subject's medical history, please assess reportability of the event.' answered with 'As of now medical records have not been received and we can not change the name until we obtain the records. ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 17:59:39
Query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' answered with 'As of now medical records have not been received and we can not change the name until we obtain the records. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 17:59:35
Data point term sent to Coder	System	24 Nov 2020 17:52:42
User closed query 'For coding purposes, THYROIDECTOMY is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from System).	System	24 Nov 2020 17:51:53
Query 'For coding purposes, THYROIDECTOMY is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' answered with 'We do not have the medical records at this time, we can not change the procedure name.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 17:51:53

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'For coding purposes, THYROIDECTOMY is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from System).	Coder Import (b) (4)	24 Nov 2020 15:44:09
User opened query 'PV Query: Please consider updating the event term to the condition for which the surgery was performed. If the condition was part of the subject's medical history, please assess reportability of the event.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 13:35:07
User opened query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 04:22:48
User closed query 'PV Query: Please consider updating the event term to the condition for which the surgery was performed.' (Site from Safety).	(b) (4), (b) (6)	21 Nov 2020 01:27:30
Query 'PV Query: Please consider updating the event term to the condition for which the surgery was performed.' answered with 'Patient had a thyroidectomy.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 13:47:29
User opened query 'PV Query: Please consider updating the event term to the condition for which the surgery was performed.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 20:48:38
User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroidectomy, LLT: Thyroidectomy - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 17:41:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 23:21:24
Data point term sent to Coder	System	05 Nov 2020 23:20:21
User entered 'Thyroidectomy'	Joanna Gurrola (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:28:53
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:28:56
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:28:58
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 20:33:36
User entered '01 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:33:36
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:29:05
User entered '30 Oct 2020'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:00:52
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Nov 2020 17:52:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 17:52:43
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Nov 2020 17:44:41
User entered '17:00' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 17:44:41
User entered empty.	Joanna Gurrola (b) (4)	05 Nov 2020 23:19:41
	(b) (4)	

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 17:52:43
User entered '30 Oct 2020 17:00'	System	24 Nov 2020 17:44:41
User entered empty.	System	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:31:25
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:31:29
User entered '1 Nov 2020'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:31:30
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:31:33
User entered 'Grade 3/Severe (Grade 3/Severe)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:31:39
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:31:45
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:31:47
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:31:48
User entered 'I'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:31:50
User entered '30 Oct 2020'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:32:17
User entered '1 Nov 2020'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:40:22
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:40:24
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:40:26
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:40:27
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:40:29
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:03:17
User entered 'Not Related (NOT RELATED)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:40:59
User entered 'Not Related (NOT RELATED)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:04:41
Query 'PV Query: As the last dose of study drug was given on 10 Sep 2020, please update the action taken with study drug from none to not applicable' answered with 'Action taken with investigational product has been updated.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 17:54:15
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 17:53:49
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 17:53:49
User opened query 'PV Query: As the last dose of study drug was given on 10 Sep 2020, please update the action taken with study drug from none to not applicable' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 13:34:56
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:41:07
User closed query 'PV Query: As the last dose of study drug was given on 10 Sep 2020, please update the action taken with study drug from none to not applicable' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 13:47:35
Query 'PV Query: As the last dose of study drug was given on 10 Sep 2020, please update the action taken with study drug from none to not applicable' answered with 'none. ' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 20:49:07
User opened query 'PV Query: As the last dose of study drug was given on 10 Sep 2020, please update the action taken with study drug from none to not applicable' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 17:35:51
User entered 'None (NONE)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:43:10
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'The medication that was given was : Levothyroxine. This medication has been added to Con Medications. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 17:58:43
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 04:22:59
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:43:13
User entered 'I'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:43:15
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:43:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:43:51
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Per discharge summary, the subject thyroidectomy was due to event #3, metastatic papillary thyroid carcinoma. Please consider upgrading event #3 to an SAE and combine the details from event #1 to event #3.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 13:35:19
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:43:53
User closed query 'PV Query: Please provide a thyroid pathology report if available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 13:47:53
User closed 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)	16 Nov 2020 13:47:50
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 13:47:46
Query 'PV Query: Please provide a thyroid pathology report if available.' answered with 'Hospital records and all obtained documents have been emailed to Safety_Moderna@iqvia.com' (Site from Safety).	Uche Ehiemua (b) (4)	14 Nov 2020 17:52:13
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.' answered with 'Hospital records and all obtained documents have been emailed to Safety_Moderna@iqvia.com' (Site from Safety).	Uche Ehiemua (b) (4)	14 Nov 2020 17:52:09
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Hospital records and all obtained documents have been emailed to Safety_Moderna@iqvia.com' (Site from Safety).	Uche Ehiemua (b) (4)	14 Nov 2020 17:52:05
User opened query 'PV Query: Please provide a thyroid pathology report if available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 17:36:31

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[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)	13 Nov 2020 17:36:22
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 17:36:12
User entered 'Patient had schedule thyroidectomy and Joanna Gurrola was observed for 36 hours at the hospital.'	(b) (4) (b) (4)	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 23:19:41

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Adverse event](#)

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)	05 Nov 2020 23:24:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	05 Nov 2020 23:24:25
Data point term sent to Coder	System	05 Nov 2020 23:23:27
User entered 'Hypothyroidism'	Joanna Gurrola (b) (4)	05 Nov 2020 23:22:51
	(b) (4)	

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[None](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	05 Nov 2020 23:23:15
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	05 Nov 2020 23:22:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:23:15
User entered 'patient will be on levothyroxine.'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Patient had a schedule thyroidectomy and now she will be on levothyroxine.'	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms malignant and unspecified, HLT: Thyroid neoplasms malignant, PT: Thyroid cancer metastatic, LLT: Thyroid cancer metastatic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 20:50:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 20:50:48
Data point term sent to Coder	System	14 Nov 2020 17:37:43
Coding entries removed.	Uche Ehiemua (b) (4) (b) (4)	14 Nov 2020 17:37:02
User entered 'metastatic papillary thyroid carcinoma' reason for change: Data Entry Error	Uche Ehiemua (b) (4) (b) (4)	14 Nov 2020 17:37:02
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms malignant and unspecified, HLT: Thyroid neoplasms malignant, PT: Thyroid cancer, LLT: Thyroid cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:00:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:00:28
Data point term sent to Coder	System	06 Nov 2020 20:30:03
User entered 'unspecified left thyroid cancer'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '22 Sep 2020'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	06 Nov 2020 20:31:27
User entered empty; reason for change Data Entry Error	Uche Ehiemua (b) (4)	06 Nov 2020 20:31:27
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	06 Nov 2020 20:29:45
User entered '00:00'	Uche Ehiemua (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:31:27
User entered '22 Sep 2020 00:00'	System	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	06 Nov 2020 20:31:27
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	06 Nov 2020 20:31:27
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	06 Nov 2020 20:29:45
User entered '30 Oct 2020'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	06 Nov 2020 20:31:27
User entered empty; reason for change Data Entry Error	Uche Ehiemua (b) (4)	06 Nov 2020 20:31:27
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	06 Nov 2020 20:29:45
User entered '00:00'	Uche Ehiemua (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:31:27
User entered '30 Oct 2020 00:00'	System	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:31:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 20:31:27
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Uche Ehiemua (b) (4)	06 Nov 2020 20:31:27
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:29:45
User entered empty.	Uche Ehiemua (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:31:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 20:31:27
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:31:27
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:29:45
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:31:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 20:31:27
User entered 'None (NONE)' reason for change: Data Entry Error	Uche Ehiemua (b) (4)	06 Nov 2020 20:31:27
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:29:45
User entered empty.	Uche Ehiemua (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[None](#)

Audit	User	Time (GMT)
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM). User entered 'I'	(b) (4), (b) (6)	23 Nov 2020 04:23:52
	Uche Ehiemua (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Uche Ehiemua (b) (4)	06 Nov 2020 20:31:27
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Uche Ehiemua (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Nov 2020 20:29:45

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:51:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 20:29:45

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:51:06

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:22:32

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

[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: LOVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 06:59:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 06:59:12
Data point term sent to Coder	System	14 Aug 2020 20:25:18
User entered 'lovastatin'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:24:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:24:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertriglyceridemia'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:24:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:24:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:24:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:24:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:24:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:24:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:24:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:24:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 16:53:36
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Shannon Moyer (b) (4)	14 Aug 2020 20:29:33
answered with 'data correct as is per source.' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 20:24:18
User entered 'un Jan 2020'	Shannon Moyer (b) (4)	14 Aug 2020 20:24:18
	(b) (4)	

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:24:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:24:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:24:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:24:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 20:24:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 20:24:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 20:24:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

[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)	15 Aug 2020 00:12:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:12:31
Data point term sent to Coder	System	14 Aug 2020 20:25:21
User entered 'montelukast'	Shannon Moyer (b) (4)	14 Aug 2020 20:25:10
	(b) (4)	

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:25:10

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Line #5 has stop date UNJAN2010. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 20:27:46
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Line #5 has stop date UNJAN2010. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF. ' answered with 'Medical history condition updated.' (Site from DM).	Joanna Gurrola (b) (4) (b) (4)	21 Sep 2020 19:37:14
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Line #5 has stop date UNJAN2010. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 10:17:06
User entered 'seasonal allergies'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:25:10

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:25:10

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:25:10

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:25:10

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:25:10

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:25:10

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:25:10

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:25:10

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 16:53:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Shannon Moyer (b) (4)	14 Aug 2020 20:29:30
answered with 'data correct as is per source.' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 20:25:10
User entered 'un Jan 2020'	Shannon Moyer (b) (4)	14 Aug 2020 20:25:10
	(b) (4)	

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:25:10

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

[Ongoing?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: The corresponding Medical History has resolved, however the medication is still ongoing. Please verify and update stop dates for Medical History and/or medication as appropriate. Otherwise, provide clarification for continued use of medication. ' canceled (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 10:16:59
User opened query 'Per DM CLR: The corresponding Medical History has resolved, however the medication is still ongoing. Please verify and update stop dates for Medical History and/or medication as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 10:15:23
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:25:10

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:25:10

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:25:10

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 20:25:10

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 20:25:10

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 20:25:10

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

[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)	17 Aug 2020 13:51:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 13:51:21
Data point term sent to Coder Coding entries removed.	System Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 13:49:52 17 Aug 2020 13:49:19
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)	15 Aug 2020 06:56:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 06:56:11
Data point term sent to Coder User entered 'metoprolol'	System Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:26:23 14 Aug 2020 20:26:09

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:26:09

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension' reason for change: Data Entry Error	Shannon Moyer (b) (4)	17 Aug 2020 13:49:19
User entered 'metoprolol'	Shannon Moyer (b) (4)	14 Aug 2020 20:26:09

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:26:09

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:26:09

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:26:09

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:26:09

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:26:09

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:26:09

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:26:09

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 16:53:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Shannon Moyer (b) (4)	14 Aug 2020 20:29:26
answered with 'data correct as is per source.' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 20:26:09
User entered 'un UNK 2010'	Shannon Moyer (b) (4)	14 Aug 2020 20:26:09
	(b) (4)	

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:26:09

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:26:09

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:26:09

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:26:09

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 20:26:09

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 20:26:09

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 20:26:09

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:12:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:12:44
Data point term sent to Coder	System	14 Aug 2020 20:29:30
User entered 'metformin'	Shannon Moyer (b) (4)	14 Aug 2020 20:29:19
	(b) (4)	

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:29:19

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'type 2 diabetes'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:29:19

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000/500'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:29:19

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:29:19

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:29:19

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:29:19

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered '1000 in the morning and 500 at night'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:29:19

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:29:19

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:29:19

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 16:53:49
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Shannon Moyer (b) (4)	14 Aug 2020 20:29:23
answered with 'data correct as is per source.' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 20:29:19
User entered 'un UNK 2010'	Shannon Moyer (b) (4)	14 Aug 2020 20:29:19
	(b) (4)	

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:29:19

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:29:19

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:29:19

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:29:19

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:29:19

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:29:19

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:29:19

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 04:11:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 04:11:45
Data point term sent to Coder	System	02 Oct 2020 04:10:09
User entered 'Tylenol'	Nancy Torrence (b) (4)	02 Oct 2020 04:09:17
	(b) (4)	

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	02 Oct 2020 04:09:17

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'Headache'	Nancy Torrence (b) (4) (b) (4)	02 Oct 2020 04:09:17

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Nancy Torrence (b) (4) (b) (4)	02 Oct 2020 04:09:17

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Nancy Torrence (b) (4) (b) (4)	02 Oct 2020 04:09:17

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	02 Oct 2020 04:09:17

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Nancy Torrence (b) (4) (b) (4)	02 Oct 2020 04:09:17

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	02 Oct 2020 04:09:17

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Nancy Torrence (b) (4) (b) (4)	02 Oct 2020 04:09:17

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	02 Oct 2020 04:09:17

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	02 Oct 2020 04:09:17

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Nancy Torrence (b) (4) (b) (4)	02 Oct 2020 04:09:17

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	02 Oct 2020 04:09:17

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	02 Oct 2020 04:09:17

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	02 Oct 2020 04:09:17

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 04:09:17

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 04:09:17

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 04:09:17

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 18:07:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 18:07:19
Data point term sent to Coder	System	06 Nov 2020 18:06:22
User entered 'Influenza Vaccine'	(b) (4), (b) (6) (b) (4)	06 Nov 2020 18:06:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 18:06:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'Influenza Virus'	(b) (4), (b) (6)	06 Nov 2020 18:06:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '180'	(b) (4), (b) (6)	06 Nov 2020 18:06:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	06 Nov 2020 18:06:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'mcg'	(b) (4), (b) (6)	06 Nov 2020 18:06:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	06 Nov 2020 18:06:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:06:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	06 Nov 2020 18:06:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:06:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	(b) (4), (b) (6)	06 Nov 2020 18:06:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 18:06:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 18:06:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	(b) (4), (b) (6)	06 Nov 2020 18:06:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 18:06:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:06:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:06:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:06:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

[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) (b) (4)	06 Nov 2020 18:09:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 18:09:21
Data point term sent to Coder	System	06 Nov 2020 18:08:24
User entered 'Levothyroxine'	(b) (4), (b) (6) (b) (4)	06 Nov 2020 18:07:36

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 18:07:36

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypothyroidism'	(b) (4), (b) (6)	06 Nov 2020 18:07:36

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '150'	(b) (4), (b) (6)	06 Nov 2020 18:07:36

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	06 Nov 2020 18:07:36

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'mcg'	(b) (4), (b) (6)	06 Nov 2020 18:07:36

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	06 Nov 2020 18:07:36

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:07:36

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Nov 2020 18:07:36

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:07:36

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 18:07:36

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 18:07:36

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 18:07:36

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:07:36

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 18:07:36

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:07:36

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:07:36

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:07:36

US3252166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:51:06

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 16:44:20
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:25:22
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	14 Aug 2020 20:29:44

US3252166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 10:51:06

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 16:45:46

US3252166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 10:51:06

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'LEFT CERVICAL LYMPH NODE EXCISION' reason for change: Data Entry Error	Uche Ehiemua (b) (4)	06 Nov 2020 20:16:33
User entered 'CERVICAL LYMPH NODE EXCISION'	(b) (4), (b) (6)	01 Oct 2020 16:45:46

US3252166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 10:51:06

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Response noted, However corresponding AE has not recorded yet, please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 19:13:29
Query 'Per CDM: Response noted, However corresponding AE has not recorded yet, please review and update accordingly.' answered with 'Ae eCRF has been updated with associated condition, metastatic papillary thyroid carcinoma' (Site from DM).	Uche Ehiemua (b) (4) (b) (4)	14 Nov 2020 17:36:44
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Uche Ehiemua (b) (4) (b) (4)	14 Nov 2020 17:36:00
User opened query 'Per CDM: Response noted, However corresponding AE has not recorded yet, please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 08:34:04
User closed query 'Per DM CLR: Please review the indication = DIAGNOSTIC as the recorded procedure is therapeutic in nature and not being done for diagnostic purposes. Please confirm if procedure is done for a MedHistory or AE condition and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 08:34:04
Query 'Per DM CLR: Please review the indication = DIAGNOSTIC as the recorded procedure is therapeutic in nature and not being done for diagnostic purposes. Please confirm if procedure is done for a MedHistory or AE condition and update as appropriate, otherwise provide clarification.' answered with 'Procedure was done for an AE condition, updated in AE eCRF' (Site from DM).	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:16:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:16:33
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 20:53:07
User entered 'Medical History (MH)' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	05 Nov 2020 20:52:30

US3252166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 10:51:06

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the indication = DIAGNOSTIC as the recorded procedure is therapeutic in nature and not being done for diagnostic purposes. Please confirm if procedure is done for a MedHistory or AE condition and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 04:36:59
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	01 Oct 2020 16:45:46

US3252166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 10:51:06

If indication is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 16:45:46

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'USA-US108-2020-MRNA-1273-P301000015'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'No (N)'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'No (N)'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'No (N)'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'No (N)'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'No (N)'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'Joel'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'Solis'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered '5201 N. 10th Street'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'Mcallen'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'TX'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'carmpa'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	06 Nov 2020 22:31:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 22:31:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'USA-US108-2020-MRNA-1273-P301000015'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'No (N)'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'No (N)'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'No (N)'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'No (N)'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'No (N)'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'Joel'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'Solis'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered '5201 N. 10th Street'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'Mcallen'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'TX'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:31:37
User entered 'carmpa'	System	06 Nov 2020 22:30:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	06 Nov 2020 22:31:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 22:31:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:51:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '06/Nov/2020 22:31'	System	06 Nov 2020 22:31:55

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:51:06

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)	06 Nov 2020 22:31:55