

US3252166 (Prod: Centex Studies Inc)

Generated By: KC Joubran

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US3252166

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

Participant ID

US3252166

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

US3252166

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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

US3252166

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

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

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

Date of Informed Consent (*dd MMM yyyy*) 13 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 00:14:47

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Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 00:14:47

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Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

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)

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

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)

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

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)

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

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)	_____

US3252166

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

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)

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

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)

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

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)

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

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

US3252166

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	UN OCT 2002
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 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)

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

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)

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

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)

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

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

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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)	_____

US3252166

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

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

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

Date of assessment (*dd MMM yyyy*) 13 AUG 2020

Is the participant of childbearing potential? Yes
No

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) UN JAN 2017

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 00:14:47

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

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 13 AUG 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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 (<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
Temperature (<i>xxx.x</i>)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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

US3252166

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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		

US3252166

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:59

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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: 09 Jun 2021 16:10:59

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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: 09 Jun 2021 16:10:59

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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: 09 Jun 2021 16:10:59

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

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

TIMEPOINT

DAY 2

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	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: 09 Jun 2021 16:10:59

TIMEPOINT

DAY 3

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	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: 09 Jun 2021 16:10:59

TIMEPOINT

DAY 4

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

16 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: 09 Jun 2021 16:10:59

TIMEPOINT

DAY 5

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	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: 09 Jun 2021 16:10:59

TIMEPOINT

DAY 6

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

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: 09 Jun 2021 16:10:59

TIMEPOINT

DAY 7

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

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:59

Yes

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

	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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

	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: 09 Jun 2021 16:10:59

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

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:59

Yes

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

	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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

	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

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

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

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252166

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 00:14:42

Generated On: 09 Jun 2021 16:10:59

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

Data signed: (b) (4) 05 Mar 2021 00:14:42

Generated On: 09 Jun 2021 16:10:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252166

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 00:14:42

Generated On: 09 Jun 2021 16:10:59

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

Data signed: (b) (4) 05 Mar 2021 00:14:42

Generated On: 09 Jun 2021 16:10:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252166

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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)

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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

US3252166

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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) 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
Right Arm

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

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 10 SEP 2020

Collection time (*00:00-23:59*) 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

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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

US3252166

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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: 09 Jun 2021 16:10:59

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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: 09 Jun 2021 16:10:59

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

TIMEPOINT

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	11 SEP 2020 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: 09 Jun 2021 16:10:59

TIMEPOINT

DAY 3

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	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: 09 Jun 2021 16:10:59

TIMEPOINT

DAY 4

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 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: 09 Jun 2021 16:10:59

TIMEPOINT

DAY 5

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

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: 09 Jun 2021 16:10:59

TIMEPOINT

DAY 6

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

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: 09 Jun 2021 16:10:59

TIMEPOINT

DAY 7

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	16 SEP 2020 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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

	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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

	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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

	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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

	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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

	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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

	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

Data signed: (b) (4) 05 Mar 2021 00:14:42

Generated On: 09 Jun 2021 16:10:59

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

Data signed: (b) (4) 05 Mar 2021 00:14:42

Generated On: 09 Jun 2021 16:10:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252166

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 00:14:42

Generated On: 09 Jun 2021 16:10:59

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

Data signed: (b) (4) 05 Mar 2021 00:14:42

Generated On: 09 Jun 2021 16:10:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252166

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

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

Data signed: (b) (4) 05 Mar 2021 00:14:47

Generated On: 09 Jun 2021 16:10:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252166

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 10 OCT 2020

Collection time (*00:00-23:59*) 09:54 (24 HR)

Collection date and time (derived) 10 OCT 2020 09:54

US3252166

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 00:14:48

Generated On: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 18:53:30
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: 09 Jun 2021 16:10:59

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 20:20:51
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: 09 Jun 2021 16:10:59

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 12:48:07
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: 09 Jun 2021 16:10:59

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 08:06:45
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: 09 Jun 2021 16:10:59

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

Date and time of submission 26 DEC 2020 08:34:09

Patient Cloud Open Date & Time 26 DEC 2020 00:01

Patient Cloud Close Date & Time 30 DEC 2020 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 00:23:24
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: 09 Jun 2021 16:10:59

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

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 09 JAN 2021 07:40:10

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: 09 Jun 2021 16:10:59

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 JAN 2021 09:33:33
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: 09 Jun 2021 16:10:59

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

Date and time of submission 23 JAN 2021 09:15:38

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: 09 Jun 2021 16:10:59

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

Date and time of submission 30 JAN 2021 07:18:37

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: 09 Jun 2021 16:10:59

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 07:48:14
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: 09 Jun 2021 16:10:59

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 15:28:51
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: 09 Jun 2021 16:10:59

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 FEB 2021 09:34:14
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: 09 Jun 2021 16:10:59

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAR 2021 06:50:44
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: 09 Jun 2021 16:10:59

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 13:09:36
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: 09 Jun 2021 16:10:59

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 MAR 2021 23:51:38
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: 09 Jun 2021 16:10:59

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 MAR 2021 12:25:40
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: 09 Jun 2021 16:10:59

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 MAR 2021 08:16:45
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: 09 Jun 2021 16:10:59

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 APR 2021 06:56:18
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: 09 Jun 2021 16:10:59

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 07:54:01
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: 09 Jun 2021 16:10:59

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 APR 2021 06:58:11
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: 09 Jun 2021 16:10:59

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 APR 2021 00:35:30
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: 09 Jun 2021 16:10:59

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAY 2021 19:37:19
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: 09 Jun 2021 16:10:59

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 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: 09 Jun 2021 16:10:59

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

TIMEPOINT

DAY 285

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 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: 09 Jun 2021 16:10:59

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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
Yes

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission	
Patient Cloud Open Date & Time	05 JUN 2021 00:01
Patient Cloud Close Date & Time	09 JUN 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

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: 09 Jun 2021 16:10:59

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
Yes

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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 Yes

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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
Yes

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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
Yes

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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	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: 09 Jun 2021 16:10:59

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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	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: 09 Jun 2021 16:10:59

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

TIMEPOINT

DAY 390

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 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: 09 Jun 2021 16:10:59

TIMEPOINT

DAY 397

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 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: 09 Jun 2021 16:10:59

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 09 Jun 2021 16:10:59

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 09 Jun 2021 16:10:59

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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
Yes

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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
Yes

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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
Yes

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 09 Jun 2021 16:10:59

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 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: 09 Jun 2021 16:10:59

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

Patient Cloud Open Date & Time	01 JAN 2022 00:01
Patient Cloud Close Date & Time	05 JAN 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 09 Jun 2021 16:10:59

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 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: 09 Jun 2021 16:10:59

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 05 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: 09 Jun 2021 16:10:59

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 09 Jun 2021 16:10:59

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

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: 09 Jun 2021 16:10:59

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 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: 09 Jun 2021 16:10:59

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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

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: 09 Jun 2021 16:10:59

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 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: 09 Jun 2021 16:10:59

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 Yes

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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 Yes

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

Patient Cloud Open Date & Time	09 APR 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: 09 Jun 2021 16:10:59

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
Yes

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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
Yes

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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	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: 09 Jun 2021 16:10:59

TIMEPOINT

DAY 642

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 09 Jun 2021 16:10:59

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission	
Patient Cloud Open Date & Time	28 MAY 2022 00:01
Patient Cloud Close Date & Time	01 JUN 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 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: 09 Jun 2021 16:10:59

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
Yes

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 09 Jun 2021 16:10:59

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#) 29 JUN 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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 Yes

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 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: 09 Jun 2021 16:10:59

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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
Yes

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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 Yes

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

TIMEPOINT

DAY 733

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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
Yes

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

Patient Cloud Open Date & Time	20 AUG 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: 09 Jun 2021 16:10:59

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 09 Jun 2021 16:10:59

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2022 00:01
Patient Cloud Close Date & Time	14 SEP 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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
Yes

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 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: 09 Jun 2021 16:10:59

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
Yes

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

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

US3252166

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:10:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 06:51:11

US3252166

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:17:16

Generated On: 09 Jun 2021 16:10:59

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

Data signed: (b) (4) 05 Mar 2021 20:17:16

Generated On: 09 Jun 2021 16:10:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252166

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 19:51:17

Generated On: 09 Jun 2021 16:10:59

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

Data signed: (b) (4) 05 Mar 2021 20:17:16

Generated On: 09 Jun 2021 16:10:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252166

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 19:51:17

Generated On: 09 Jun 2021 16:10:59

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 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:17:16

Generated On: 09 Jun 2021 16:10:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252166

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 19:51:17

Generated On: 09 Jun 2021 16:10:59

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 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 19:51:17

Generated On: 09 Jun 2021 16:10:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252166

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 19:51:17

Generated On: 09 Jun 2021 16:10:59

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 25 MAR 2021

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

Folder OID VISIT4

US3252166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 19:51:17

Generated On: 09 Jun 2021 16:10:59

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3252166

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 19:51:17

Generated On: 09 Jun 2021 16:10:59

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 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 19:51:17

Generated On: 09 Jun 2021 16:10:59

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 25 MAR 2021

Collection time (*00:00-23:59*) 08:01 (24 HR)

Collection date and time (derived) 25 MAR 2021 08:01

US3252166

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 19:51:17

Generated On: 09 Jun 2021 16:10:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252166

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

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 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3252166

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

Generate Next COVID-19 Assessment

Yes

No

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 19:51:16

Generated On: 09 Jun 2021 16:10:59

Date of updated informed consent (<i>dd MMM yyyy</i>)	8 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	8 FEB 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 8 FEB 2021

Collection time (*00:00-23:59*) 10:12 (24 HR)

Collection date and time (derived) 8 FEB 2021 10:12

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 8 FEB 2021

Collection time (*00:00 - 23:59*) 10:12

Collection Date and Time (derived) 8 FEB 2021 10:12

US3252166

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

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 (2)

Data signed: (b) (4) 22 Apr 2021 18:48:55

Generated On: 09 Jun 2021 16:10:59

AEID

Adverse event

HYPOTHYROIDISM

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

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

Yes

No

Start date (dd MMM yyyy)

30 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

PRODUCTION RELEASE (v12.003

327 of 1964

EAB) (1725)

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 18:48:55

Generated On: 09 Jun 2021 16:10:59

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

328 of 1964

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 18:48:55

Generated On: 09 Jun 2021 16:10:59

AEID USA-US108-2020-MRNA-1273-P30
1000019

Adverse event METASTATIC PAPILLARY
THYROID CARCINOMA

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) 22 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

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
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening True

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

PRODUCTION RELEASE (v12.003 329 of 1964
EAB) (1725)

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 18:48:55

Generated On: 09 Jun 2021 16:10:59

Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication False

Concomitant Procedure True

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 18:48:55

Generated On: 09 Jun 2021 16:10:59

SUBJECT WAS EVALUATED
DUE TO WORSENING
SWELLING OF A LEFT
CERVICAL LYMPH NODE ON
THE 15TH OF SEP 2020 AN
EXCISIONAL BIOPSY WAS
RECOMMENDED AND
SCHEDULED FOR THE 22TH OF
SEP 2020. BIOPSY REPORT WAS
POSITIVE FOR POSSIBLE
METASTATIC PAPILLARY
THYROID CARCINOMA AND
WAS REFERRED TO
ENDOCRINOLOGIST/SURGEON
FOR EVALUATION ON THE 7TH
OF OCT 2020. SUBJECT WAS
EVALUATED ON OCT THE 7TH
2020 BY HER
ENDOCRINOLOGIST AND THE
DIAGNOSIS OF METASTATIC
PAPILLARY THYROID
CARCINOMA WAS CONFIRMED.
THE SUBJECT WAS SCHEDULED
FOR A TOTAL
THYROIDECTOMY ON OCT
30TH 2020. SUBJECTS'
THYROIDECTOMY WAS
SUCCESSFUL AND WAS
DISCHARGE ON OCT 31ST 2020.

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)	

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

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)

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

Name of Medication LOVASTATIN

Prophylaxis Yes
No

Indication HYPERTRIGLYCERIDEMIA

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

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 JAN 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

Name of Medication MONTELUKAST

Prophylaxis Yes
No

Indication SEASONAL ALLERGIES

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

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 JAN 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

Name of Medication METOPROLOL

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 100

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

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
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

Name of Medication METFORMIN

Prophylaxis Yes
No

Indication TYPE 2 DIABETES

Dose per administration 1000/500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

1000 IN THE MORNING AND 500
AT NIGHT

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

Name of Medication TYLENOL

Prophylaxis Yes
No

Indication HEADACHE

Dose per administration 500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

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*) 12 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 13 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes
No

Indication INFLUENZA VIRUS

Dose per administration 180

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify MCG

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 26 AUG 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 26 AUG 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

Name of Medication LEVOTHYROXINE

Prophylaxis Yes
No

Indication HYPOTHYROIDISM

Dose per administration 150

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify MCG

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

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*) 30 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3252166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3252166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Mar 2021 20:17:15

Generated On: 09 Jun 2021 16:10:59

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 SEP 2020	LEFT CERVICAL LYMPH NODE EXCISION	Adverse Event	
30 OCT 2020	TYROIDECTOMY	Adverse Event	

US3252166

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

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-P301000019

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 18:48:55

Generated On: 09 Jun 2021 16:10:59

SAEID	USA-US108-2020-MRNA-1273-P30 1000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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)	4

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 18:48:55

Generated On: 09 Jun 2021 16:10:59

SAEID	USA-US108-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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)	4
Date of submission (Pre-filled from custom function)	06/DEC/2020 17:27
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.	<input checked="" type="checkbox"/> True

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 18:48:55

Generated On: 09 Jun 2021 16:10:59

SAEID	USA-US108-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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)	4
Date of submission (Pre-filled from custom function)	12/FEB/2021 10:47
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.	<input checked="" type="checkbox"/> True

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form (3)

Data signed: (b) (4) 22 Apr 2021 18:48:55

Generated On: 09 Jun 2021 16:10:59

SAEID	USA-US108-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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)	4
Date of submission (Pre-filled from custom function)	25/FEB/2021 11:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form (4)

Data signed: (b) (4) 22 Apr 2021 18:48:55

Generated On: 09 Jun 2021 16:10:59

SAEID	USA-US108-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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)	4
Date of submission (Pre-filled from custom function)	13/APR/2021 13:01
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: 09 Jun 2021 16:10:59

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'US3252166'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:14:07

US3252166

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	14 Aug 2020 20:10:07
	(b) (4)	

US3252166

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:14:08

US3252166

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4)	14 Aug 2020 20:10:07
	(b) (4)	

US3252166

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'SCRN'	System	14 Aug 2020 20:10:07

US3252166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:59

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered (b) (6) 1970'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:14:09

US3252166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:59

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '50'	Shannon Moyer (b) (4)	14 Aug 2020 20:10:42
	(b) (4)	

US3252166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:59

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'YEARS'	System	14 Aug 2020 20:10:42

US3252166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:59

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '50'	System	13 Aug 2020 21:30:31

US3252166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:59

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Female (F)'	Shannon Moyer (b) (4)	14 Aug 2020 20:10:42
	(b) (4)	

US3252166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:59

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Shannon Moyer (b) (4)	14 Aug 2020 20:10:42
	(b) (4)	

US3252166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:59

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '1'	Shannon Moyer (b) (4)	14 Aug 2020 20:10:42
	(b) (4)	

US3252166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:59

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	14 Aug 2020 20:10:42
	(b) (4)	

US3252166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:59

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	14 Aug 2020 20:10:42
	(b) (4)	

US3252166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:59

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	14 Aug 2020 20:10:42
	(b) (4)	

US3252166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:59

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	14 Aug 2020 20:10:42
	(b) (4)	

US3252166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	14 Aug 2020 20:10:42
	(b) (4)	

US3252166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:59

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:10:42
	(b) (4)	

US3252166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:59

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	14 Aug 2020 20:10:42
	(b) (4)	

US3252166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:59

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	14 Aug 2020 20:10:42
	(b) (4)	

US3252166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:59

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 21:30:31

US3252166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Aug 2020'	System	13 Aug 2020 21:30:31

US3252166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2020'	System	13 Aug 2020 21:30:31

US3252166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:59

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	13 Aug 2020 21:30:31

US3252166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 21:30:31

US3252166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:59

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:30:31

US3252166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:59

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:30:31

US3252166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:59

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:30:31

US3252166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:59

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:14:08

US3252166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:59

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'I'	System	13 Aug 2020 21:30:41

US3252166

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 21:30:41

US3252166

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:10:59

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	14 Aug 2020 20:11:04
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User coded data point as SOC: Metabolism and nutrition disorders, HLG: 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)	15 Aug 2020 00:11:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(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)	14 Aug 2020 20:11:38
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'un UNK 2010'	Shannon Moyer (b) (4)	14 Aug 2020 20:11:38
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	14 Aug 2020 20:11:38
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	14 Aug 2020 20:11:38
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:11:38
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	14 Aug 2020 20:11:38
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Jan 2010'	System	14 Aug 2020 20:11:38

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2010'	System	14 Aug 2020 20:11:38

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered empty.	System	14 Aug 2020 20:11:38

US3252166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered empty.	System	14 Aug 2020 20:11:38

US3252166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:10:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'un UNK 2010'	Shannon Moyer (b) (4)	14 Aug 2020 20:11:53
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:10:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	14 Aug 2020 20:11:53
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:10:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	14 Aug 2020 20:11:53
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:11:53
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:10:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	14 Aug 2020 20:11:53
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:10:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Jan 2010'	System	14 Aug 2020 20:11:53

US3252166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:10:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2010'	System	14 Aug 2020 20:11:53

US3252166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered empty.	System	14 Aug 2020 20:11:53

US3252166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered empty.	System	14 Aug 2020 20:11:53

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Lipid metabolism disorders, HLT: Elevated triglycerides, PT: Hypertriglyceridaemia, LLT: Hypertriglyceridemia - 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	System	14 Aug 2020 20:12:53
User entered 'hypertriglyceridemia'	Shannon Moyer (b) (4)	14 Aug 2020 20:12:29
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'un Jan 2020'	Shannon Moyer (b) (4)	14 Aug 2020 20:12:29
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	14 Aug 2020 20:12:29
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	14 Aug 2020 20:12:29
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:12:29
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	14 Aug 2020 20:12:29
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Jan 2020'	System	14 Aug 2020 20:12:29

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2020'	System	14 Aug 2020 20:12:29

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered empty.	System	14 Aug 2020 20:12:29

US3252166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered empty.	System	14 Aug 2020 20:12:29

US3252166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:10:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User coded data point as SOC: Immune system disorders, HLG: 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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'un UNK 2015'	Shannon Moyer (b) (4)	14 Aug 2020 20:13:02
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:10:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	14 Aug 2020 20:13:02
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:10:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	14 Aug 2020 20:13:02
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:13:02
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:10:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	14 Aug 2020 20:13:02
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:10:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Jan 2015'	System	14 Aug 2020 20:13:02

US3252166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:10:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2015'	System	14 Aug 2020 20:13:02

US3252166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered empty.	System	14 Aug 2020 20:13:02

US3252166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered empty.	System	14 Aug 2020 20:13:02

US3252166

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:10:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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.	(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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'un Jan 2010'	Shannon Moyer (b) (4)	21 Aug 2020 17:19:17
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:10:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 17:19:17
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:10:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (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: 09 Jun 2021 16:10:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 17:19:17
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:10:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Jan 2010'	System	21 Aug 2020 17:19:17

US3252166

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:10:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2010'	System	21 Aug 2020 17:19:17

US3252166

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
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: 09 Jun 2021 16:10:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to animal, LLT: Allergy to animals - version MedDRA\23.0.	Coder Import (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)	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)	21 Aug 2020 17:20:05
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'un Jan 2010'	Shannon Moyer (b) (4)	21 Aug 2020 17:20:05
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:10:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 17:20:05
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:10:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 17:20:05
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'un Jan 2010'	Shannon Moyer (b) (4)	21 Aug 2020 17:20:05
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:10:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 17:20:05
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:10:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Jan 2010'	System	21 Aug 2020 17:20:05

US3252166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:10:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2010'	System	21 Aug 2020 17:20:05

US3252166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Jan 2010'	System	21 Aug 2020 17:20:05

US3252166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2010'	System	21 Aug 2020 17:20:05

US3252166

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:10:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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) (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) (b) (4)	21 Aug 2020 17:22:18
Data point term sent to Coder System	System	21 Aug 2020 17:21:05
User entered 'cholecystectomy'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 17:20:29

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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'un Jan 2007'	Shannon Moyer (b) (4)	21 Aug 2020 17:20:29
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:10:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 17:20:29
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:10:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 17:20:29
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'un Jan 2007'	Shannon Moyer (b) (4)	21 Aug 2020 17:20:29
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:10:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 17:20:29
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:10:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Jan 2007'	System	21 Aug 2020 17:20:29

US3252166

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:10:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2007'	System	21 Aug 2020 17:20:29

US3252166

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Jan 2007'	System	21 Aug 2020 17:20:29

US3252166

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2007'	System	21 Aug 2020 17:20:29

US3252166

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:10:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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)	21 Aug 2020 17:22:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'un Oct 2007'	Shannon Moyer (b) (4)	21 Aug 2020 17:20:52
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:10:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 17:20:52
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:10:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 17:20:52
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'un Oct 2007'	Shannon Moyer (b) (4)	21 Aug 2020 17:20:52
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:10:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 17:20:52
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:10:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Oct 2007'	System	21 Aug 2020 17:20:52

US3252166

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:10:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2007'	System	21 Aug 2020 17:20:52

US3252166

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Oct 2007'	System	21 Aug 2020 17:20:52

US3252166

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2007'	System	21 Aug 2020 17:20:52

US3252166

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:10:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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)	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)	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)	21 Aug 2020 17:21:22
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'un Oct 2002'	Shannon Moyer (b) (4)	21 Aug 2020 17:21:22
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:10:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 17:21:22
	(b) (4)	

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Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:10:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 17:21:22
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'un Oct 2002'	Shannon Moyer (b) (4)	21 Aug 2020 17:21:22
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:10:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 17:21:22
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:10:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Oct 2002'	System	21 Aug 2020 17:21:22

US3252166

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:10:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2002'	System	21 Aug 2020 17:21:22

US3252166

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Oct 2002'	System	21 Aug 2020 17:21:22

US3252166

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2002'	System	21 Aug 2020 17:21:22

US3252166

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:10:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'un Jan 2017'	Shannon Moyer (b) (4)	21 Aug 2020 17:21:50
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:10:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 17:21:50
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:10:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 17:21:50
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'un Jan 2017'	Shannon Moyer (b) (4)	21 Aug 2020 17:21:50
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:10:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 17:21:50
	(b) (4)	

US3252166

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:10:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Jan 2017'	System	21 Aug 2020 17:21:50

US3252166

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2017'	System	21 Aug 2020 17:21:50

US3252166

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Jan 2017'	System	21 Aug 2020 17:21:50

US3252166

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2017'	System	21 Aug 2020 17:21:50

US3252166

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:10:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User coded data point as SOC: Hepatobiliary disorders, HLG: 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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'UN Jan 2007'	(b) (4), (b) (6)	29 Sep 2020 21:09:40

US3252166

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:10:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 21:09:40

US3252166

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:10:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 21:09:40

US3252166

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'UN Jan 2007'	(b) (4), (b) (6)	29 Sep 2020 21:09:40

US3252166

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:10:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 21:09:40

US3252166

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:10:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Jan 2007'	System	29 Sep 2020 21:09:40

US3252166

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:10:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2007'	System	29 Sep 2020 21:09:40

US3252166

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Jan 2007'	System	29 Sep 2020 21:09:40

US3252166

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2007'	System	29 Sep 2020 21:09:40

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:10:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine myoma - 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.	(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)	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'UN Jan 2017'	(b) (4), (b) (6)	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:10:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:10:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'UN Jan 2017'	(b) (4), (b) (6)	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:10:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:10:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Jan 2017'	System	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:10:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2017'	System	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'Jan 2017'	System	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '2017'	System	29 Sep 2020 21:10:14

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	14 Aug 2020 20:15:56
	(b) (4)	

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '13 Aug 2020'	Shannon Moyer (b) (4)	14 Aug 2020 20:15:56
	(b) (4)	

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '15:53'	Shannon Moyer (b) (4)	14 Aug 2020 20:15:56
	(b) (4)	

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered '13 Aug 2020 15:53'	System	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
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: 09 Jun 2021 16:10:59

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
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: 09 Jun 2021 16:10:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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	(b) (4)	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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'	(b) (4)	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'bpm'	System	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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'	(b) (4)	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'breaths/min'	System	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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'	(b) (4)	14 Aug 2020 20:15:56
	Shannon Moyer (b) (4)	
	(b) (4)	

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'mmHg'	System	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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'	(b) (4)	
	Shannon Moyer (b) (4)	14 Aug 2020 20:15:56
	(b) (4)	

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User entered 'mmHg'	System	14 Aug 2020 20:15:56

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33

US3252166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33

US3252166

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	14 Aug 2020 20:16:16
	(b) (4)	

US3252166

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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).	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: 09 Jun 2021 16:10:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '13 Aug 2020'	Shannon Moyer (b) (4)	14 Aug 2020 20:17:18
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:10:59

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	Shannon Moyer (b) (4)	14 Aug 2020 20:17:18
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Surgically sterile (SURGICALLY STERILE)'	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:17:18

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:10:59

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:17:18
	(b) (4)	

US3252166

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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	Nancy Torrence (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

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:10:59

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	14 Aug 2020 20:17:18
	(b) (4)	

US3252166

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:17:18
	(b) (4)	

US3252166

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:10:59

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	Shannon Moyer (b) (4)	14 Aug 2020 20:17:18
	(b) (4)	

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:31:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:59

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '1'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 21:31:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:40:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 21:31:30

US3252166

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	14 Aug 2020 20:18:01
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '13 Aug 2020'	Shannon Moyer (b) (4)	14 Aug 2020 20:18:01
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4)	14 Aug 2020 20:18:01
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'VISIT1'	System	14 Aug 2020 20:18:01

US3252166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:29:31

US3252166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:59

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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)	13 Aug 2020 21:29:31

US3252166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:29:31

US3252166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:48

US3252166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:48

US3252166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 21:31:48

US3252166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:59

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 21:31:48

US3252166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:59

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 21:31:48

US3252166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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	(b) (4)	
	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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	(b) (4)	
	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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	(b) (4)	
	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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	(b) (4)	
	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '13 Aug 2020'	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '15:53'	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '98.8' F	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '76'	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'bpm'	System	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '16'	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'breaths/min'	System	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '122'	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'mmHg'	System	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '79'	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'mmHg'	System	14 Aug 2020 20:19:52

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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	(b) (4)	
	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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	(b) (4)	
	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '13 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:23:52
User entered empty.	(b) (4)	
	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '98.7' F reason for change: Data Entry	Shannon Moyer (b) (4)	21 Aug 2020 17:23:52
Error	(b) (4)	
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Oral (Oral)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:23:52
User entered empty.	(b) (4)	
	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '76' reason for change: Data Entry	Shannon Moyer (b) (4)	21 Aug 2020 17:23:52
Error	(b) (4)	
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '15' reason for change: Data Entry	Shannon Moyer (b) (4)	21 Aug 2020 17:23:52
Error	(b) (4)	
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'breaths/min'	System	21 Aug 2020 17:23:52
User entered empty.	System	14 Aug 2020 20:19:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '136' reason for change: Data Entry	Shannon Moyer (b) (4)	21 Aug 2020 17:23:52
Error	(b) (4)	
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:19:52
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '85' reason for change: Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:23:52
User entered empty.	(b) (4)	14 Aug 2020 20:19:52
	Shannon Moyer (b) (4)	
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 17:24:24
User entered '13 Aug 2020'	(b) (4)	
	Shannon Moyer (b) (4)	14 Aug 2020 20:20:14
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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)	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 Mahoney (b) (4)	13 Aug 2020 23:03:14

US3252166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Joanna Gurrola Mahoney (b) (4)	13 Aug 2020 23:03:14

US3252166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Joanna Gurrola Mahoney (b) (4)	13 Aug 2020 23:03:14

US3252166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '13 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	13 Aug 2020 23:03:14

US3252166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '17:04'	Joanna Gurrola Mahoney (b) (4)	13 Aug 2020 23:03:14

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered '13 Aug 2020 17:04'	System	13 Aug 2020 23:03:14

US3252166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola Mahoney (b) (4)	13 Aug 2020 23:03:14

US3252166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	14 Aug 2020 20:21:25
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '13 Aug 2020'	Shannon Moyer (b) (4)	14 Aug 2020 20:21:25
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '16:44'	Shannon Moyer (b) (4)	14 Aug 2020 20:21:25
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '13 Aug 2020'	Shannon Moyer (b) (4)	14 Aug 2020 20:21:42
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	14 Aug 2020 20:21:42
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '16:33'	Shannon Moyer (b) (4)	14 Aug 2020 20:21:42
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	Shannon Moyer (b) (4)	14 Aug 2020 20:21:42
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Shannon Moyer (b) (4)	14 Aug 2020 20:21:42
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered empty.	System	14 Aug 2020 20:21:42

US3252166

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	14 Aug 2020 20:21:46
	(b) (4)	

US3252166

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'I'	System	14 Aug 2020 20:21:46

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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'	System	14 Aug 2020 01:52:28
User entered '97.3'	System	14 Aug 2020 01:52:28

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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-ae3-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: 09 Jun 2021 16:10:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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-ae3-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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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-ae3-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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'Yes (Y)'	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: 09 Jun 2021 16:10:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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
	System	15 Aug 2020 21:41:36

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '97.0'	System	17 Aug 2020 22:33:42
	System	17 Aug 2020 22:33:42

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '17 Aug 2020 17:33'	System	17 Aug 2020 22:33:42
	System	17 Aug 2020 22:33:42

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '97.0'	System	19 Aug 2020 12:11:22
	System	19 Aug 2020 12:11:22

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '19 Aug 2020 07:11'	System	19 Aug 2020 12:11:22
	System	19 Aug 2020 12:11:22

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '96.2'	System	20 Aug 2020 03:05:01
	System	20 Aug 2020 03:05:01

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '19 Aug 2020 22:04'	System	20 Aug 2020 03:05:01
	System	20 Aug 2020 03:05:01

US3252166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '13 Aug 2020 18:05'	System	13 Aug 2020 23:05:12
	System	13 Aug 2020 23:05:12

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (1)'	System	14 Aug 2020 01:53:21
	System	14 Aug 2020 01:53:21

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	System	14 Aug 2020 01:53:21
	System	14 Aug 2020 01:53:21

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (1)'	System	14 Aug 2020 01:53:21
	System	14 Aug 2020 01:53:21

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '13 Aug 2020 20:53'	System	14 Aug 2020 01:53:21
	System	14 Aug 2020 01:53:21

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	System	14 Aug 2020 19:50:21
	System	14 Aug 2020 19:50:21

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '14 Aug 2020 14:50'	System	14 Aug 2020 19:50:21
	System	14 Aug 2020 19:50:21

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '16 Aug 2020 14:18'	System	16 Aug 2020 19:18:27
	System	16 Aug 2020 19:18:27

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (1)'	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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	System	20 Aug 2020 03:05:17
	System	20 Aug 2020 03:05:17

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '19 Aug 2020 22:05'	System	20 Aug 2020 03:05:17
	System	20 Aug 2020 03:05:17

US3252166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No interference with activity (1)'	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: 09 Jun 2021 16:10:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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
	System	13 Aug 2020 23:05:41

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' 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: 09 Jun 2021 16:10:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' 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: 09 Jun 2021 16:10:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' 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: 09 Jun 2021 16:10:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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
	System	13 Aug 2020 23:05:41

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	14 Aug 2020 01:54:17
	System	14 Aug 2020 01:54:17

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	14 Aug 2020 01:54:17
	System	14 Aug 2020 01:54:17

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	14 Aug 2020 19:51:07
	System	14 Aug 2020 19:51:07

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	14 Aug 2020 19:51:07
	System	14 Aug 2020 19:51:07

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	14 Aug 2020 19:51:07
	System	14 Aug 2020 19:51:07

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	14 Aug 2020 19:51:07
	System	14 Aug 2020 19:51:07

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	14 Aug 2020 19:51:07
	System	14 Aug 2020 19:51:07

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	14 Aug 2020 19:51:07
	System	14 Aug 2020 19:51:07

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	System	14 Aug 2020 19:51:07
	System	14 Aug 2020 19:51:07

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	15 Aug 2020 21:42:21
	System	15 Aug 2020 21:42:21

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	15 Aug 2020 21:42:21
	System	15 Aug 2020 21:42:21

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	15 Aug 2020 21:42:21
	System	15 Aug 2020 21:42:21

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	15 Aug 2020 21:42:21
	System	15 Aug 2020 21:42:21

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	15 Aug 2020 21:42:21
	System	15 Aug 2020 21:42:21

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	System	15 Aug 2020 21:42:21
	System	15 Aug 2020 21:42:21

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '15 Aug 2020 16:42'	System	15 Aug 2020 21:42:21
	System	15 Aug 2020 21:42:21

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	16 Aug 2020 19:18:49
	System	16 Aug 2020 19:18:49

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	16 Aug 2020 19:18:49
	System	16 Aug 2020 19:18:49

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	16 Aug 2020 19:18:49
	System	16 Aug 2020 19:18:49

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	16 Aug 2020 19:18:49
	System	16 Aug 2020 19:18:49

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	16 Aug 2020 19:18:49
	System	16 Aug 2020 19:18:49

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	16 Aug 2020 19:18:49
	System	16 Aug 2020 19:18:49

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	System	16 Aug 2020 19:18:49
	System	16 Aug 2020 19:18:49

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '16 Aug 2020 14:18'	System	16 Aug 2020 19:18:49
	System	16 Aug 2020 19:18:49

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	17 Aug 2020 22:34:16
	System	17 Aug 2020 22:34:16

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	17 Aug 2020 22:34:16
	System	17 Aug 2020 22:34:16

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	17 Aug 2020 22:34:16
	System	17 Aug 2020 22:34:16

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '17 Aug 2020 17:34'	System	17 Aug 2020 22:34:16
	System	17 Aug 2020 22:34:16

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	System	19 Aug 2020 12:11:55
	System	19 Aug 2020 12:11:55

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '19 Aug 2020 07:11'	System	19 Aug 2020 12:11:55
	System	19 Aug 2020 12:11:55

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	20 Aug 2020 03:05:48
	System	20 Aug 2020 03:05:48

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	20 Aug 2020 03:05:48
	System	20 Aug 2020 03:05:48

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	20 Aug 2020 03:05:48
	System	20 Aug 2020 03:05:48

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	20 Aug 2020 03:05:48
	System	20 Aug 2020 03:05:48

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	20 Aug 2020 03:05:48
	System	20 Aug 2020 03:05:48

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	20 Aug 2020 03:05:48
	System	20 Aug 2020 03:05:48

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	System	20 Aug 2020 03:05:48
	System	20 Aug 2020 03:05:48

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '19 Aug 2020 22:05'	System	20 Aug 2020 03:05:48
	System	20 Aug 2020 03:05:48

US3252166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	23 Aug 2020 21:45:32
	(b) (4)	

US3252166

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '21 Aug 2020'	Shannon Moyer (b) (4)	23 Aug 2020 21:45:32
	(b) (4)	

US3252166

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	23 Aug 2020 21:45:32
	(b) (4)	

US3252166

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Shannon Moyer (b) (4)	23 Aug 2020 21:45:32
	(b) (4)	

US3252166

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	23 Aug 2020 21:45:39
	(b) (4)	

US3252166

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered '1'	System	23 Aug 2020 21:45:39

US3252166

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	28 Aug 2020 15:18:33
	(b) (4)	

US3252166

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered '27 Aug 2020'	Shannon Moyer (b) (4)	28 Aug 2020 15:18:33
	(b) (4)	

US3252166

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	28 Aug 2020 15:18:33
	(b) (4)	

US3252166

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered empty.	Shannon Moyer (b) (4)	28 Aug 2020 15:18:33
	(b) (4)	

US3252166

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	28 Aug 2020 15:18:39
	(b) (4)	

US3252166

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'I'	System	28 Aug 2020 15:18:39

US3252166

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	05 Sep 2020 21:20:36
	(b) (4)	

US3252166

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered '5 Sep 2020'	Nancy Torrence (b) (4)	05 Sep 2020 21:20:36
	(b) (4)	

US3252166

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	05 Sep 2020 21:20:36
	(b) (4)	

US3252166

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered empty.	Nancy Torrence (b) (4)	05 Sep 2020 21:20:36
	(b) (4)	

US3252166

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	05 Sep 2020 21:20:57
	(b) (4)	

US3252166

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered '1'	System	05 Sep 2020 21:20:57

US3252166

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	11 Sep 2020 22:06:36
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '10 Sep 2020'	Shannon Moyer (b) (4)	11 Sep 2020 22:06:36
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4)	11 Sep 2020 22:06:36
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'VISIT2'	System	11 Sep 2020 22:06:36

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '10 Sep 2020'	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '14:23'	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '98.0' F	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '77'	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'bpm'	System	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '16'	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '118'	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'mmHg'	System	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '77'	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'mmHg'	System	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '10 Sep 2020'	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '16:15'	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '97.7' F	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '72'	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'bpm'	System	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '15'	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '126'	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'mmHg'	System	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '77'	Shannon Moyer (b) (4)	11 Sep 2020 22:08:04
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'mmHg'	System	11 Sep 2020 22:08:04

US3252166

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	Shannon Moyer (b) (4)	11 Sep 2020 22:08:15
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Shannon Moyer (b) (4)	11 Sep 2020 22:08:15
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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)	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 Mahoney (b) (4)	10 Sep 2020 20:45:28

US3252166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Joanna Gurrola Mahoney (b) (4)	10 Sep 2020 20:45:28

US3252166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Joanna Gurrola Mahoney (b) (4)	10 Sep 2020 20:45:28

US3252166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '10 Sep 2020'	Joanna Gurrola Mahoney (b) (4)	10 Sep 2020 20:45:28

US3252166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '15:29'	Joanna Gurrola Mahoney (b) (4)	10 Sep 2020 20:45:28

US3252166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola Mahoney (b) (4)	10 Sep 2020 20:45:28

US3252166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	11 Sep 2020 22:09:13
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '10 Sep 2020'	Shannon Moyer (b) (4)	11 Sep 2020 22:09:13
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '14:32'	Shannon Moyer (b) (4)	11 Sep 2020 22:09:13
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '10 Sep 2020'	Shannon Moyer (b) (4)	11 Sep 2020 22:09:33
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	11 Sep 2020 22:09:33
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '14:28'	Shannon Moyer (b) (4)	11 Sep 2020 22:09:33
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'No (N)'	Shannon Moyer (b) (4)	11 Sep 2020 22:09:33
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Shannon Moyer (b) (4)	11 Sep 2020 22:09:33
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered empty.	System	11 Sep 2020 22:09:33

US3252166

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	11 Sep 2020 22:09:43
	(b) (4)	

US3252166

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered '1'	System	11 Sep 2020 22:09:43

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '97.7'	System	10 Sep 2020 21:16:28
	System	10 Sep 2020 21:16:28

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'Yes (Y)'	System	11 Sep 2020 00:15:33
	System	11 Sep 2020 00:15:33

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '96.0'	System	11 Sep 2020 00:15:33
	System	11 Sep 2020 00:15:33

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	System	11 Sep 2020 00:15:33
	System	11 Sep 2020 00:15:33

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '97.5'	System	11 Sep 2020 20:46:39
	System	11 Sep 2020 20:46:39

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'Yes (Y)'	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: 09 Jun 2021 16:10:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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
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)	29 Sep 2020 21:08:37
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	12 Sep 2020 17:01:57
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: 09 Jun 2021 16:10:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'Yes (Y)'	System	14 Sep 2020 01:36:27
	System	14 Sep 2020 01:36:27

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '94.6'	System	14 Sep 2020 01:36:27
	System	14 Sep 2020 01:36:27

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '13 Sep 2020 20:36'	System	14 Sep 2020 01:36:27
	System	14 Sep 2020 01:36:27

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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
	System	15 Sep 2020 02:05:21

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'Yes (Y)'	System	16 Sep 2020 00:40:30
	System	16 Sep 2020 00:40:30

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '97.2'	System	17 Sep 2020 01:52:16
	System	17 Sep 2020 01:52:16

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '16 Sep 2020 20:52'	System	17 Sep 2020 01:52:16
	System	17 Sep 2020 01:52:16

US3252166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '10 Sep 2020 16:16'	System	10 Sep 2020 21:16:45
	System	10 Sep 2020 21:16:45

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (1)'	System	11 Sep 2020 00:16:53
	System	11 Sep 2020 00:16:53

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	System	11 Sep 2020 00:16:53
	System	11 Sep 2020 00:16:53

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (1)'	System	11 Sep 2020 00:16:53
	System	11 Sep 2020 00:16:53

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '10 Sep 2020 19:16'	System	11 Sep 2020 00:16:53
	System	11 Sep 2020 00:16:53

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'Does not interfere with activity (2)'	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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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'	System	12 Sep 2020 17:02:32
User entered '12 Sep 2020 12:01'	System	12 Sep 2020 17:02:32

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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'	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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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'	System	15 Sep 2020 02:05:41
User entered 'None (1)'	System	15 Sep 2020 02:05:41

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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'	System	15 Sep 2020 02:05:41
User entered 'None (1)'	System	15 Sep 2020 02:05:41

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' 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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (1)'	System	17 Sep 2020 01:52:34
	System	17 Sep 2020 01:52:34

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (1)'	System	17 Sep 2020 01:52:34
	System	17 Sep 2020 01:52:34

US3252166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	System	10 Sep 2020 22:39:47
	System	10 Sep 2020 22:39:47

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '10 Sep 2020 16:17'	System	10 Sep 2020 22:39:47
	System	10 Sep 2020 22:39:47

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' 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: 09 Jun 2021 16:10:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' 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: 09 Jun 2021 16:10:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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'	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: 09 Jun 2021 16:10:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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
	System	11 Sep 2020 00:17:21

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' 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: 09 Jun 2021 16:10:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' 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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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'	System	11 Sep 2020 00:17:21
User entered '10 Sep 2020 19:17'	System	11 Sep 2020 00:17:21

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	11 Sep 2020 20:48:03
	System	11 Sep 2020 20:48:03

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: '50d3dfc-cc2d-4014-bf43-889394efe1b1' User entered 'None (0)'	System	11 Sep 2020 20:48:03
	System	11 Sep 2020 20:48:03

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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'	System	11 Sep 2020 20:48:03
User entered 'No (N)'	System	11 Sep 2020 20:48:03

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '11 Sep 2020 15:47'	System	11 Sep 2020 20:48:03
	System	11 Sep 2020 20:48:03

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	12 Sep 2020 17:03:17
	System	12 Sep 2020 17:03:17

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	12 Sep 2020 17:03:17
	System	12 Sep 2020 17:03:17

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	12 Sep 2020 17:03:17
	System	12 Sep 2020 17:03:17

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '12 Sep 2020 12:02'	System	12 Sep 2020 17:03:17
	System	12 Sep 2020 17:03:17

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	14 Sep 2020 01:37:07
	System	14 Sep 2020 01:37:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	14 Sep 2020 01:37:07
	System	14 Sep 2020 01:37:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	14 Sep 2020 01:37:07
	System	14 Sep 2020 01:37:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	14 Sep 2020 01:37:07
	System	14 Sep 2020 01:37:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	14 Sep 2020 01:37:07
	System	14 Sep 2020 01:37:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	14 Sep 2020 01:37:07
	System	14 Sep 2020 01:37:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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-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: 09 Jun 2021 16:10:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	16 Sep 2020 00:41:31
	System	16 Sep 2020 00:41:31

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	16 Sep 2020 00:41:31
	System	16 Sep 2020 00:41:31

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	16 Sep 2020 00:41:31
	System	16 Sep 2020 00:41:31

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	16 Sep 2020 00:41:31
	System	16 Sep 2020 00:41:31

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	16 Sep 2020 00:41:31
	System	16 Sep 2020 00:41:31

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'None (0)'	System	16 Sep 2020 00:41:31
	System	16 Sep 2020 00:41:31

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	System	16 Sep 2020 00:41:31
	System	16 Sep 2020 00:41:31

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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
	System	17 Sep 2020 01:53:07

US3252166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' 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: 09 Jun 2021 16:10:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' 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: 09 Jun 2021 16:10:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered 'No (N)'	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: 09 Jun 2021 16:10:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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' User entered '16 Sep 2020 20:53'	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: 09 Jun 2021 16:10:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	18 Sep 2020 03:34:54
	(b) (4)	

US3252166

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered '17 Sep 2020'	Nancy Torrence (b) (4)	18 Sep 2020 03:34:54
	(b) (4)	

US3252166

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	18 Sep 2020 03:34:54
	(b) (4)	

US3252166

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered empty.	Nancy Torrence (b) (4)	18 Sep 2020 03:34:54
	(b) (4)	

US3252166

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	18 Sep 2020 03:34:59
	(b) (4)	

US3252166

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'I'	System	18 Sep 2020 03:34:59

US3252166

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	25 Sep 2020 01:47:36
	(b) (4)	

US3252166

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered '24 Sep 2020'	Nancy Torrence (b) (4)	25 Sep 2020 01:47:36
	(b) (4)	

US3252166

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	25 Sep 2020 01:47:36
	(b) (4)	

US3252166

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered empty.	Nancy Torrence (b) (4)	25 Sep 2020 01:47:36
	(b) (4)	

US3252166

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:42
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	25 Sep 2020 01:47:39
	(b) (4)	

US3252166

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered '1'	System	25 Sep 2020 01:47:39

US3252166

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	02 Oct 2020 03:24:12
	(b) (4)	

US3252166

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered '1 Oct 2020'	Nancy Torrence (b) (4)	02 Oct 2020 03:24:12
	(b) (4)	

US3252166

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	02 Oct 2020 03:24:12
	(b) (4)	

US3252166

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered empty.	Nancy Torrence (b) (4)	02 Oct 2020 03:24:12
	(b) (4)	

US3252166

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	02 Oct 2020 03:24:16
	(b) (4)	

US3252166

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered '1'	System	02 Oct 2020 03:24:16

US3252166

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'VISIT3'	System	12 Oct 2020 22:30:52

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'bpm'	System	12 Oct 2020 22:31:21

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'breaths/min'	System	12 Oct 2020 22:31:21

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'mmHg'	System	12 Oct 2020 22:31:21

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'mmHg'	System	12 Oct 2020 22:31:21

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04

US3252166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04

US3252166

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 10:56:52
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Sample is NOT missing in PPD, requisition number is 1F617404067. Reports were sent back on 20 Jan.' (Site from DM).	Joanna Gurrola Mahoney	09 Feb 2021 17:03:52
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 05:55:48
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: 09 Jun 2021 16:10:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
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: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 00:14:49
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: 09 Jun 2021 16:10:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered '1'	System	12 Oct 2020 22:31:54

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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'	System	27 Oct 2020 11:10:25
User entered 'No (N)'	System	27 Oct 2020 11:10:25

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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'	System	27 Oct 2020 11:10:25
User entered 'No (N)'	System	27 Oct 2020 11:10:25

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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'	System	13 Nov 2020 04:36:24
User entered 'No (N)'	System	13 Nov 2020 04:36:24

US3252166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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'	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: 09 Jun 2021 16:10:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:10:53
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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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'	System	25 Nov 2020 02:27:41
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: 09 Jun 2021 16:10:59

[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'	System	25 Nov 2020 02:27:41
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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2020-12-01T18:53:23', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '30356746-5079-4b32-a830-bed8ee38d931'	System	02 Dec 2020 00:53:33
User entered 'No (N)'	System	02 Dec 2020 00:53:33

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2020-12-01T18:53:26', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '30356746-5079-4b32-a830-bed8ee38d931'	System	02 Dec 2020 00:53:33
User entered 'No (N)'	System	02 Dec 2020 00:53:33

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2020-12-01T18:53:30', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '30356746-5079-4b32-a830-bed8ee38d931'	System	02 Dec 2020 00:53:33
User entered '01 Dec 2020 18:53:30'	System	02 Dec 2020 00:53:33

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2020-12-05T20:20:45', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '7ec5e77e-14be-422d-881c-a7da4275af3b'	System	06 Dec 2020 02:20:56
User entered 'No (N)'	System	06 Dec 2020 02:20:56

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2020-12-05T20:20:47', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '7ec5e77e-14be-422d-881c-a7da4275af3b'	System	06 Dec 2020 02:20:56
User entered 'No (N)'	System	06 Dec 2020 02:20:56

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2020-12-05T20:20:51', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '7ec5e77e-14be-422d-881c-a7da4275af3b'	System	06 Dec 2020 02:20:56
User entered '05 Dec 2020 20:20:51'	System	06 Dec 2020 02:20:56

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2020-12-13T12:48:02', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '59eaf47e-579e-437f-bcc2-0411967b1727'	System	13 Dec 2020 18:48:09
User entered 'No (N)'	System	13 Dec 2020 18:48:09

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2020-12-13T12:48:04', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '59eaf47e-579e-437f-bcc2-0411967b1727'	System	13 Dec 2020 18:48:09
User entered 'No (N)'	System	13 Dec 2020 18:48:09

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2020-12-13T12:48:07', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '59eaf47e-579e-437f-bcc2-0411967b1727' User entered '13 Dec 2020 12:48:07'	System	13 Dec 2020 18:48:09
	System	13 Dec 2020 18:48:09

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2020-12-19T08:06:23', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'fdce8851-2181-4b61-9efe-b340bad6fe30'	System	19 Dec 2020 14:06:48
User entered 'No (N)'	System	19 Dec 2020 14:06:48

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2020-12-19T08:06:31', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'fdce8851-2181-4b61-9efe-b340bad6fe30'	System	19 Dec 2020 14:06:48
User entered 'No (N)'	System	19 Dec 2020 14:06:48

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2020-12-19T08:06:45', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'fdce8851-2181-4b61-9efe-b340bad6fe30'	System	19 Dec 2020 14:06:48
User entered '19 Dec 2020 08:06:45'	System	19 Dec 2020 14:06:48

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2020-12-26T08:34:04', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '13e452c1-a261-4ca9-92f0-3e6e8dce9cb1'	System	26 Dec 2020 14:34:12
User entered 'No (N)'	System	26 Dec 2020 14:34:12

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2020-12-26T08:34:06', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '13e452c1-a261-4ca9-92f0-3e6e8dce9cb1'	System	26 Dec 2020 14:34:12
User entered 'No (N)'	System	26 Dec 2020 14:34:12

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2020-12-26T08:34:09', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '13e452c1-a261-4ca9-92f0-3e6e8dce9cb1' User entered '26 Dec 2020 08:34:09'	System	26 Dec 2020 14:34:12
	System	26 Dec 2020 14:34:12

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2021-01-02T00:23:09', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '1e53be32-ad72-4acc-8224-0a396b03f6d9'	System	02 Jan 2021 06:23:27
User entered 'No (N)'	System	02 Jan 2021 06:23:27

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2021-01-02T00:23:15', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '1e53be32-ad72-4acc-8224-0a396b03f6d9'	System	02 Jan 2021 06:23:27
User entered 'No (N)'	System	02 Jan 2021 06:23:27

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2021-01-02T00:23:24', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '1e53be32-ad72-4acc-8224-0a396b03f6d9' User entered '02 Jan 2021 00:23:24'	System	02 Jan 2021 06:23:27
	System	02 Jan 2021 06:23:27

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2021-01-09T07:39:46', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a53dfb45-9ca7-4785-bf43-32d2b11433a6'	System	09 Jan 2021 13:40:13
User entered 'No (N)'	System	09 Jan 2021 13:40:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2021-01-09T07:39:55', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a53dfb45-9ca7-4785-bf43-32d2b11433a6'	System	09 Jan 2021 13:40:13
User entered 'No (N)'	System	09 Jan 2021 13:40:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2021-01-09T07:40:10', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'a53dfb45-9ca7-4785-bf43-32d2b11433a6' User entered '09 Jan 2021 07:40:10'	System	09 Jan 2021 13:40:13
	System	09 Jan 2021 13:40:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2021-01-16T09:33:25', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '30634bae-7712-4fba-9e7e-d77dccbc5d36'	System	16 Jan 2021 15:33:35
User entered 'No (N)'	System	16 Jan 2021 15:33:35

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[Have you been exposed to someone with 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: '2021-01-16T09:33:27', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '30634bae-7712-4fba-9e7e-d77dccbc5d36'	System	16 Jan 2021 15:33:35
User entered 'No (N)'	System	16 Jan 2021 15:33:35

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2021-01-16T09:33:33', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '30634bae-7712-4fba-9e7e-d77dccbc5d36' User entered '16 Jan 2021 09:33:33'	System	16 Jan 2021 15:33:35
	System	16 Jan 2021 15:33:35

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2021-01-23T09:15:32', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '643e3985-a56e-491b-a783-008ed44754d3'	System	23 Jan 2021 15:15:41
User entered 'No (N)'	System	23 Jan 2021 15:15:41

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2021-01-23T09:15:34', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '643e3985-a56e-491b-a783-008ed44754d3' User entered 'No (N)'	System	23 Jan 2021 15:15:41
	System	23 Jan 2021 15:15:41

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2021-01-23T09:15:38', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '643e3985-a56e-491b-a783-008ed44754d3'	System	23 Jan 2021 15:15:41
User entered '23 Jan 2021 09:15:38'	System	23 Jan 2021 15:15:41

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2021-01-30T07:18:29', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8e24ed8c-f33b-419a-96a4-055772c49813' User entered 'No (N)'	System	30 Jan 2021 13:18:39
	System	30 Jan 2021 13:18:39

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2021-01-30T07:18:32', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8e24ed8c-f33b-419a-96a4-055772c49813'	System	30 Jan 2021 13:18:39
User entered 'No (N)'	System	30 Jan 2021 13:18:39

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2021-01-30T07:18:37', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '8e24ed8c-f33b-419a-96a4-055772c49813' User entered '30 Jan 2021 07:18:37'	System	30 Jan 2021 13:18:39
	System	30 Jan 2021 13:18:39

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2021-02-06T07:48:08', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'c7832ca1-9b38-4006-b77a-b51b87a2d9c4'	System	06 Feb 2021 13:48:18
User entered 'No (N)'	System	06 Feb 2021 13:48:18

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2021-02-06T07:48:11', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'c7832ca1-9b38-4006-b77a-b51b87a2d9c4'	System	06 Feb 2021 13:48:18
User entered 'No (N)'	System	06 Feb 2021 13:48:18

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2021-02-06T07:48:14', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'c7832ca1-9b38-4006-b77a-b51b87a2d9c4'	System	06 Feb 2021 13:48:18
User entered '06 Feb 2021 07:48:14'	System	06 Feb 2021 13:48:18

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2021-02-13T15:28:44', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9f8a4860-588a-4649-9f05-86fbf71f4b02'	System	13 Feb 2021 21:28:54
User entered 'No (N)'	System	13 Feb 2021 21:28:54

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2021-02-13T15:28:48', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9f8a4860-588a-4649-9f05-86fbf71f4b02'	System	13 Feb 2021 21:28:54
User entered 'No (N)'	System	13 Feb 2021 21:28:54

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2021-02-13T15:28:51', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '9f8a4860-588a-4649-9f05-86fbf71f4b02'	System	13 Feb 2021 21:28:54
User entered '13 Feb 2021 15:28:51'	System	13 Feb 2021 21:28:54

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2021-02-20T09:34:07', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '65f08f80-5390-4d7c-820c-2ea16d2d5149'	System	20 Feb 2021 15:34:17
User entered 'No (N)'	System	20 Feb 2021 15:34:17

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2021-02-20T09:34:09', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '65f08f80-5390-4d7c-820c-2ea16d2d5149'	System	20 Feb 2021 15:34:17
User entered 'No (N)'	System	20 Feb 2021 15:34:17

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2021-02-20T09:34:14', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '65f08f80-5390-4d7c-820c-2ea16d2d5149'	System	20 Feb 2021 15:34:17
User entered '20 Feb 2021 09:34:14'	System	20 Feb 2021 15:34:17

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2021-03-02T06:50:35-06:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '1b249c5d-dd0f-4119-880e-0f35890e57a5'	System	02 Mar 2021 12:50:47
User entered 'No (N)'	System	02 Mar 2021 12:50:47

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2021-03-02T06:50:37-06:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '1b249c5d-dd0f-4119-880e-0f35890e57a5'	System	02 Mar 2021 12:50:47
User entered 'No (N)'	System	02 Mar 2021 12:50:47

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2021-03-02T06:50:44-06:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '1b249c5d-dd0f-4119-880e-0f35890e57a5'	System	02 Mar 2021 12:50:47
User entered '02 Mar 2021 06:50:44'	System	02 Mar 2021 12:50:47

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2021-03-06T13:09:31-06:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '07c82428-4c6e-4ab9-b7e1-0fd22eb75c1e'	System	06 Mar 2021 19:11:40
User entered 'No (N)'	System	06 Mar 2021 19:11:40

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2021-03-06T13:09:33-06:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '07c82428-4c6e-4ab9-b7e1-0fd22eb75c1e'	System	06 Mar 2021 19:11:40
User entered 'No (N)'	System	06 Mar 2021 19:11:40

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2021-03-06T13:09:36-06:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '07c82428-4c6e-4ab9-b7e1-0fd22eb75c1e'	System	06 Mar 2021 19:11:40
User entered '06 Mar 2021 13:09:36'	System	06 Mar 2021 19:11:40

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2021-03-13T23:51:32-06:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '4d8c229d-bc4d-4bf1-83ba-f4962aaff374'	System	14 Mar 2021 05:52:58
User entered 'No (N)'	System	14 Mar 2021 05:52:58

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2021-03-13T23:51:35-06:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '4d8c229d-bc4d-4bf1-83ba-f4962aaff374'	System	14 Mar 2021 05:52:58
User entered 'No (N)'	System	14 Mar 2021 05:52:58

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2021-03-13T23:51:38-06:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '4d8c229d-bc4d-4bf1-83ba-f4962aaff374'	System	14 Mar 2021 05:52:58
User entered '13 Mar 2021 23:51:38'	System	14 Mar 2021 05:52:58

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2021-03-20T12:25:30-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'ef6b094d-ed90-481f-9f23-806aa6913984'	System	20 Mar 2021 17:35:23
User entered 'No (N)'	System	20 Mar 2021 17:35:23

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2021-03-20T12:25:33-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'ef6b094d-ed90-481f-9f23-806aa6913984'	System	20 Mar 2021 17:35:23
User entered 'No (N)'	System	20 Mar 2021 17:35:23

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2021-03-20T12:25:40-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'ef6b094d-ed90-481f-9f23-806aa6913984'	System	20 Mar 2021 17:35:23
User entered '20 Mar 2021 12:25:40'	System	20 Mar 2021 17:35:23

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2021-03-27T08:16:40-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '0fc0587d-e573-4b94-b4f7-6fb474a9674a' User entered 'No (N)'	System	27 Mar 2021 13:16:50
	System	27 Mar 2021 13:16:50

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2021-03-27T08:16:42-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '0fc0587d-e573-4b94-b4f7-6fb474a9674a' User entered 'No (N)'	System	27 Mar 2021 13:16:50
	System	27 Mar 2021 13:16:50

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2021-03-27T08:16:45-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '0fc0587d-e573-4b94-b4f7-6fb474a9674a' User entered '27 Mar 2021 08:16:45'	System	27 Mar 2021 13:16:50
	System	27 Mar 2021 13:16:50

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2021-04-03T06:56:11-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'b3bfb60c-ce4f-4d92-97ac-9ed7901c5e80'	System	03 Apr 2021 11:56:21
User entered 'No (N)'	System	03 Apr 2021 11:56:21

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2021-04-03T06:56:13-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'b3bf60c-ce4f-4d92-97ac-9ed7901c5e80'	System	03 Apr 2021 11:56:21
User entered 'No (N)'	System	03 Apr 2021 11:56:21

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2021-04-03T06:56:18-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'b3bfb60c-ce4f-4d92-97ac-9ed7901c5e80'	System	03 Apr 2021 11:56:21
User entered '03 Apr 2021 06:56:18'	System	03 Apr 2021 11:56:21

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2021-04-10T07:53:56-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '75477aea-0db0-4a8e-863a-dda6f31d1cf3'	System	10 Apr 2021 12:54:05
User entered 'No (N)'	System	10 Apr 2021 12:54:05

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2021-04-10T07:53:57-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '75477aea-0db0-4a8e-863a-dda6f31d1cf3'	System	10 Apr 2021 12:54:05
User entered 'No (N)'	System	10 Apr 2021 12:54:05

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2021-04-10T07:54:01-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '75477aea-0db0-4a8e-863a-dda6f31d1cf3'	System	10 Apr 2021 12:54:05
User entered '10 Apr 2021 07:54:01'	System	10 Apr 2021 12:54:05

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2021-04-17T06:58:06-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '2492523a-03e5-476c-82d4-e0e4756d8379'	System	17 Apr 2021 11:58:13
User entered 'No (N)'	System	17 Apr 2021 11:58:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2021-04-17T06:58:08-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '2492523a-03e5-476c-82d4-e0e4756d8379'	System	17 Apr 2021 11:58:13
User entered 'No (N)'	System	17 Apr 2021 11:58:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2021-04-17T06:58:11-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '2492523a-03e5-476c-82d4-e0e4756d8379'	System	17 Apr 2021 11:58:13
User entered '17 Apr 2021 06:58:11'	System	17 Apr 2021 11:58:13

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2021-04-25T00:35:23-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'b54ed624-6a6e-4f55-93f2-77ec87a0b784'	System	25 Apr 2021 05:35:35
User entered 'No (N)'	System	25 Apr 2021 05:35:35

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2021-04-25T00:35:26-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'b54ed624-6a6e-4f55-93f2-77ec87a0b784'	System	25 Apr 2021 05:35:35
User entered 'No (N)'	System	25 Apr 2021 05:35:35

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2021-04-25T00:35:30-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: 'b54ed624-6a6e-4f55-93f2-77ec87a0b784'	System	25 Apr 2021 05:35:35
User entered '25 Apr 2021 00:35:30'	System	25 Apr 2021 05:35:35

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: '2021-05-01T19:37:13-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '31ee2731-6d1f-444a-a97a-1233d1bccd65'	System	02 May 2021 00:37:22
User entered 'No (N)'	System	02 May 2021 00:37:22

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

Have you been exposed to someone with 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: '2021-05-01T19:37:16-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '31ee2731-6d1f-444a-a97a-1233d1bccd65'	System	02 May 2021 00:37:22
User entered 'No (N)'	System	02 May 2021 00:37:22

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: '2021-05-01T19:37:19-05:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '31ee2731-6d1f-444a-a97a-1233d1bccd65'	System	02 May 2021 00:37:22
User entered '01 May 2021 19:37:19'	System	02 May 2021 00:37:22

US3252166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:10:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:40:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2021-03-02T06:50:58-06:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '42892534-b742-423b-8890-e1def084d498'	System	02 Mar 2021 12:51:15
User entered 'No (N)'	System	02 Mar 2021 12:51:15

US3252166

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:10:59

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:40:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A441660-1D89-4986-8897-747B6B470598)', Time: '2021-03-02T06:51:11-06:00', User OID: 'PatientReportedOutcome (US3252166)', ODM File OID: '42892534-b742-423b-8890-e1def084d498'	System	02 Mar 2021 12:51:15
User entered '02 Mar 2021 06:51:11'	System	02 Mar 2021 12:51:15

US3252166

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	06 Nov 2020 06:12:03
	(b) (4)	

US3252166

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered '5 Nov 2020'	Nancy Torrence (b) (4)	06 Nov 2020 06:12:03
	(b) (4)	

US3252166

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	06 Nov 2020 06:12:03
	(b) (4)	

US3252166

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered empty.	Nancy Torrence (b) (4)	06 Nov 2020 06:12:03
	(b) (4)	

US3252166

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	06 Nov 2020 06:12:07
	(b) (4)	

US3252166

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:48:04
User entered 'I'	System	06 Nov 2020 06:12:07

US3252166

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	31 Mar 2021 14:51:41
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	31 Mar 2021 14:29:41
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	31 Mar 2021 14:29:41
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	31 Mar 2021 14:29:41
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 04:35:51

US3252166

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
Signature has been broken.	Joanna Gurrola Mahoney	31 Mar 2021 14:51:41
	(b) (4)	
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney	31 Mar 2021 14:51:41
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered '9 Dec 2020'	Joanna Gurrola Mahoney	05 Feb 2021 04:35:51
	(b) (4)	

US3252166

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	31 Mar 2021 14:51:41
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	31 Mar 2021 14:51:41
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Contact Not Made (CONTACT NOT MADE)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 04:35:51

US3252166

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	31 Mar 2021 14:51:41
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	31 Mar 2021 14:29:47
User entered 'patient was not called for safety call and was missed.' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	31 Mar 2021 14:29:47
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'left voice mail'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 04:35:51

US3252166

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 04:35:55

US3252166

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:48
User entered '1'	System	05 Feb 2021 04:35:55

US3252166

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	31 Mar 2021 14:52:11
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	31 Mar 2021 14:52:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 04:36:15

US3252166

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
Signature has been broken.	Joanna Gurrola Mahoney	31 Mar 2021 14:52:11
	(b) (4)	
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney	31 Mar 2021 14:52:11
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered '8 Jan 2021'	Joanna Gurrola Mahoney	05 Feb 2021 04:36:15
	(b) (4)	

US3252166

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
Signature has been broken.	Joanna Gurrola Mahoney	31 Mar 2021 14:52:11
	(b) (4)	
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney	31 Mar 2021 14:52:11
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Contact Not Made (CONTACT NOT MADE)'	Joanna Gurrola Mahoney	05 Feb 2021 04:36:15
	(b) (4)	

US3252166

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
Signature has been broken.	Joanna Gurrola Mahoney	31 Mar 2021 14:52:11
	(b) (4)	
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney	31 Mar 2021 14:52:11
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'left voice mail'	Joanna Gurrola Mahoney	05 Feb 2021 04:36:15
	(b) (4)	

US3252166

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 04:36:19

US3252166

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User entered '1'	System	05 Feb 2021 04:36:19

US3252166

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	31 Mar 2021 14:57:02
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	31 Mar 2021 14:57:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 06:46:04

US3252166

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	31 Mar 2021 14:57:02
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	31 Mar 2021 14:57:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered '8 Feb 2021'	(b) (4), (b) (6)	12 Feb 2021 06:46:04

US3252166

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
Signature has been broken.	Joanna Gurrola Mahoney	31 Mar 2021 14:57:02
	(b) (4)	
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney	31 Mar 2021 14:57:02
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	12 Feb 2021 06:46:04

US3252166

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
Signature has been broken.	Joanna Gurrola Mahoney	31 Mar 2021 14:57:02
	(b) (4)	
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney	31 Mar 2021 14:57:02
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'LEFT VOICE MAIL'	(b) (4), (b) (6)	12 Feb 2021 06:46:04

US3252166

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
Signature has been broken.	(b) (4), (b) (6)	26 Mar 2021 02:50:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 02:50:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'No (N)'	(b) (4), (b) (6)	12 Feb 2021 06:46:09

US3252166

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User entered '1'	System	26 Mar 2021 02:50:18
User entered empty.	System	12 Feb 2021 06:46:09

US3252166

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 02:51:04

US3252166

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	26 Mar 2021 10:19:03
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'subject visit is out of window period' (Site from System).	(b) (4), (b) (6)	26 Mar 2021 02:54:09
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	26 Mar 2021 02:51:04
User entered '25 Mar 2021'	(b) (4), (b) (6)	26 Mar 2021 02:51:04

US3252166

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Mar 2021 02:51:04

US3252166

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User entered 'VISIT4'	System	26 Mar 2021 02:51:04

US3252166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 20:35:42

US3252166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:35:42

US3252166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:35:42

US3252166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User entered empty.	System	30 Mar 2021 20:35:42

US3252166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:35:42

US3252166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:35:42

US3252166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:35:42

US3252166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:35:42

US3252166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User entered empty.	System	30 Mar 2021 20:35:42

US3252166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:35:42

US3252166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User entered empty.	System	30 Mar 2021 20:35:42

US3252166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:35:42

US3252166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User entered empty.	System	30 Mar 2021 20:35:42

US3252166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:35:42

US3252166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User entered empty.	System	30 Mar 2021 20:35:42

US3252166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51

US3252166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51

US3252166

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered 'No (N)'	(b) (4), (b) (6)	26 Mar 2021 02:54:17

US3252166

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 02:54:17

US3252166

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 02:54:42

US3252166

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered '25 Mar 2021'	(b) (4), (b) (6)	26 Mar 2021 02:54:42

US3252166

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered '08:01'	(b) (4), (b) (6)	26 Mar 2021 02:54:42

US3252166

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User entered '25 Mar 2021 08:01'	System	26 Mar 2021 02:54:42

US3252166

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 02:54:50

US3252166

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:16:51
User entered '1'	System	26 Mar 2021 02:54:50

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 03:01:08

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered '8 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 03:01:08

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Feb 2021 03:01:08

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User entered 'UNBLND_DECIDE'	System	09 Feb 2021 03:01:08

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:10:59

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered '8 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 03:01:34

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:10:59

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:56:52

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:10:59

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 03:01:34

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:10:59

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:56:52

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:10:59

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered '8 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 03:01:34

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:10:59

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	09 Feb 2021 03:01:34

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:10:59

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	09 Feb 2021 03:01:34

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:10:59

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	09 Feb 2021 03:01:34

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:10:59

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'No (N)'	(b) (4), (b) (6)	09 Feb 2021 03:01:34

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:10:59

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User entered empty.	System	09 Feb 2021 03:01:34

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:10:59

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User entered empty.	System	09 Feb 2021 03:01:34

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 03:01:57

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered '8 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 03:01:57

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered '10:12'	(b) (4), (b) (6)	09 Feb 2021 03:01:57

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User entered '8 Feb 2021 10:12'	System	09 Feb 2021 03:01:57

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:10:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 03:02:10

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:10:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered '8 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 03:02:10

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:10:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered '10:12'	(b) (4), (b) (6)	09 Feb 2021 03:02:10

US3252166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:10:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:20
User entered '8 Feb 2021 10:12'	System	09 Feb 2021 03:02:10

US3252166

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:10:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:59:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:12:39
User entered 'No (N)'	Shannon Moyer (b) (4)	14 Aug 2020 20:22:15
	(b) (4)	

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:36:03
User coded data point as SOC: Endocrine disorders, HLT: 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.	Coder Import (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 Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:36:12
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:36:42
DataPoint Un-verified.		09 Feb 2021 17:36:38
DataPoint Verified.		09 Feb 2021 17:36:28
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:38:33
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:38:49
User entered '30 Oct 2020'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:39:02
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:39:12
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:39:14
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:39:15
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:39:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:39:22
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:39:25
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:39:27
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:39:28
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:39:30
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:39:31
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:39:33
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:39:35
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:39:37
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:39:38
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:39:40
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:39:46
User entered 'Not Related (NOT RELATED)'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:39:48
User entered 'Not Related (NOT RELATED)'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User closed query 'Per source, action taken with IP is Not Related. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 00:26:20
Query 'Per source, action taken with IP is Not Related. Please verify and update EDC accordingly.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 09:46:10
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 09:46:03
User opened query 'Per source, action taken with IP is Not Related. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:42:47
User entered 'None (NONE)'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:48:55
Signature has been broken.	mathew maran (b) (4)	21 Apr 2021 06:33:32
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:43:22
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:43:24
User entered '1'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:43:29
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:43:32
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 Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:43:34
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:23:15
User entered 'patient will be on levothyroxine.'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:43:36
User entered 'Patient had a schedule thyroidectomy and now she will be on levothyroxine.'	Joanna Gurrola Mahoney (b) (4)	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:10:59

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: 09 Jun 2021 16:10:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 23:22:51

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:10:59

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:23:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 15:46:33
Un-reviewed for Safety.		12 Feb 2021 15:46:24
DataPoint Un-verified.		12 Feb 2021 15:46:24
User entered 'USA-US108-2020-mRNA-1273-P301000019' reason for change: Data Entry Error		12 Feb 2021 15:46:24
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:40:17
Reviewed for Safety.		07 Dec 2020 18:09:46
Un-reviewed for Safety.		07 Dec 2020 18:09:40
User entered 'USA-US108-2020-mRNA-1273-P301000015' reason for change: Data Entry Error		07 Dec 2020 18:09:40
Reviewed for Safety.		06 Dec 2020 17:26:42
User entered 'USA-US108-2020-mRNA-1273-P301000019'		06 Dec 2020 17:24:59
User entered 'New'		06 Dec 2020 17:24:59

US3252166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:10:59

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:40:26
User closed query 'Per MM, please confirm if this event does not meet serious criteria due to its medical significance.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 14:26:31
Query 'Per MM, please confirm if this event does not meet serious criteria due to its medical significance.' answered with 'this has been updated.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	05 Dec 2020 16:42:06
User opened query 'Per MM, please confirm if this event does not meet serious criteria due to its medical significance.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 20:12:17
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: 09 Jun 2021 16:10:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:40:38
DataPoint Un-verified.	(b) (4)	03 Dec 2020 01:02:32
DataPoint Verified.	(b) (4)	03 Dec 2020 01:02:16
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: 09 Jun 2021 16:10:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:41:07
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: 09 Jun 2021 16:10:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:41:10
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: 09 Jun 2021 16:10:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:41:14
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: 09 Jun 2021 16:10:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:41:16
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) (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) (b) (4)	06 Nov 2020 20:29:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:10:59

[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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:10:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:41:29
User entered 'No (N)'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:10:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:43:08
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:10:59

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:43:11
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) (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) (b) (4)	06 Nov 2020 20:29:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:10:59

[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

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:43:13
User entered 'Grade 4 (Grade 4)' reason for change:	Joanna Gurrola Mahoney	05 Dec 2020 16:41:57
Data Entry Error	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Uche Ehiemua (b) (4)	06 Nov 2020 20:29:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:43:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	05 Dec 2020 16:41:57
User entered 'No (N)'	Uche Ehiemua (b) (4)	06 Nov 2020 20:29:45

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Folder: Adverse Events

Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:43:20
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:10:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:43:22
User entered '1' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	05 Dec 2020 16:41:57
User entered '0'	Uche Ehiemua (b) (4)	06 Nov 2020 20:29:45

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Folder: Adverse Events

Form: Adverse Events (3)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:43:23
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:10:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:43:49
DataPoint Un-verified.	(b) (4)	27 Jan 2021 18:43:36
DataPoint Verified.	(b) (4)	27 Jan 2021 18:43:34
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:10:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:43:50
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:10:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:43:52
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:43:54
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:43:55
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:43:57
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:43:59
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:44:03
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).	(b) (4)	06 Nov 2020 20:29:45
User entered empty.	System	06 Nov 2020 20:29:45
	Uche Ehiemua (b) (4)	06 Nov 2020 20:29:45
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:44:06
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).	(b) (4)	06 Nov 2020 20:29:45
User entered empty.	System	06 Nov 2020 20:29:45
	Uche Ehiemua (b) (4)	06 Nov 2020 20:29:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:23:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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)	25 Feb 2021 17:57:23
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 'updated' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	24 Feb 2021 20:17:29
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Feb 2021 20:17:24
User closed query 'Per source, action taken with IP is recorded as none. Please verify if source and EDC is accurate.' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 00:26:34
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)	19 Feb 2021 15:16:33
Query 'Per source, action taken with IP is recorded as none. Please verify if source and EDC is accurate.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 09:46:40
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 09:46:30
User opened query 'Per source, action taken with IP is recorded as none. Please verify if source and EDC is accurate.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:47:13
User closed query 'PV Query: For the event "metastatic papillary thyroid carcinoma", 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)	05 Feb 2021 16:50:58
Query 'PV Query: For the event "metastatic papillary thyroid carcinoma", 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 'updated' (Site from Safety).	Shannon Moyer (b) (4) (b) (4)	04 Feb 2021 06:28:17
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	04 Feb 2021 06:28:07

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Folder: Adverse Events

Form: Adverse Events (3)

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Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'PV Query: For the event "metastatic papillary thyroid carcinoma", 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)	11 Dec 2020 18:30:33
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

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:44:27
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:44:25
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:44:23
User closed 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).	(b) (4), (b) (6)	18 Dec 2020 11:38:11
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. answered with 'LEFT CERVICAL LYMPH NODE EXCISION was performed according to the CRIO' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	09 Dec 2020 14:14:43
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).	(b) (4), (b) (6)	23 Nov 2020 04:23:52
User entered 'I'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User closed query 'PV Query: Please confirm the outcome of the event metastatic papillary thyroid carcinoma, since the carcinoma was infiltrative into the anterior esophageal muscles and superficially the left recurrent laryngeal nerve. ' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 16:51:04
Query 'PV Query: Please confirm the outcome of the event metastatic papillary thyroid carcinoma, since the carcinoma was infiltrative into the anterior esophageal muscles and superficially the left recurrent laryngeal nerve. ' answered with 'LEFT CERVICAL LYMPH NODE EXCISION was performed and its recovered according to the crio' (Site from Safety).	Shannon Moyer (b) (4) (b) (4)	04 Feb 2021 06:29:00
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:52:45
User opened query 'PV Query: Please confirm the outcome of the event metastatic papillary thyroid carcinoma, since the carcinoma was infiltrative into the anterior esophageal muscles and superficially the left recurrent laryngeal nerve. ' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:39:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:31:27
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:53:30
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide excisional biopsy report if possible. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 15:38:08
Query 'PV Query: Please provide excisional biopsy report if possible. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. ' answered with 'We do not have the biopsy report. The only report we have is from the surgery to remove the mass.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 21:32:21
User opened query 'PV Query: Please provide excisional biopsy report if possible. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 15:27:42
User closed query 'PV Query: please provide excisional biopsy report if possible ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 14:21:44
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:48:55
Query 'PV Query: please provide excisional biopsy report if possible ' answered with 'medical records are in the subjects chart with biopsy report. ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 05:22:03
User opened query 'PV Query: please provide excisional biopsy report if possible ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 20:43:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:18:24
User closed query 'Hello, data still not located in source. Going forward, please do not respond to query if data has not been updated as requeries will need to be issued. Thank you.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:18:22
Query 'Hello, data still not located in source. Going forward, please do not respond to query if data has not been updated as requeries will need to be issued. Thank you.' answered with 'narrative updated ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:11:20
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 16:11:03

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject was evaluated due to worsening swelling of a left cervical lymph node on the 15th of SEP 2020 an excisional biopsy was recommended and scheduled for the 22th of SEP 2020. Biopsy report was positive for possible metastatic papillary thyroid carcinoma and was referred to endocrinologist/surgeon for evaluation on the 7th of OCT 2020. Subject was evaluated on Oct the 7th 2020 by her endocrinologist and the diagnosis of metastatic papillary thyroid carcinoma was confirmed. The subject was scheduled for a total thyroidectomy on Oct 30th 2020. Subjects' thyroidectomy was successful and was discharge on Oct 31st 2020.' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:11:03
User opened query 'Hello, data still not located in source. Going forward, please do not respond to query if data has not been updated as requeries will need to be issued. Thank you.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 14:25:14
User closed query 'Please update progress note or add source documentation which verifies the narrative included.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 14:25:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
Query 'Please update progress note or add source documentation which verifies the narrative included.' answered with 'task sent process ongoing' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 09:47:22
User opened query 'Please update progress note or add source documentation which verifies the narrative included.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:49:54
User closed query 'PV Query: Please provide information on examinations of COVID-19 during hospitalization.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 16:51:18
User closed query 'PV query: When was the neck mass detected?' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 16:51:12
User closed query 'PV Query: Please clarify date of total abdominal hysterectomy.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 16:51:07
Query 'PV Query: Please provide information on examinations of COVID-19 during hospitalization.' answered with 'no data obtainable' (Site from Safety).	Shannon Moyer (b) (4) (b) (4)	04 Feb 2021 06:35:48
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	04 Feb 2021 06:35:07

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[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	04 Feb 2021 06:35:07
User entered 'metastatic papillary thyroid carcinoma was started on 22 dec 2020 and ended on 30 oct 2020 with grade 4 intensity and was a SAE. The event was a life threatening event and the action taken was left cervical lymph node excision. the outcome is resolved and recovered' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	04 Feb 2021 06:35:07
Query 'PV query: When was the neck mass detected?' answered with 'no data available' (Site from Safety).	Shannon Moyer (b) (4) (b) (4)	04 Feb 2021 06:30:22
Query 'PV Query: Please clarify date of total abdominal hysterectomy.' answered with 'un-jan-2017' (Site from Safety).	Shannon Moyer (b) (4) (b) (4)	04 Feb 2021 06:30:04
User opened query 'PV Query: Please provide information on examinations of COVID-19 during hospitalization.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:39:27
User opened query 'PV query: When was the neck mass detected?' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:37:19
User opened query 'PV Query: Please clarify date of total abdominal hysterectomy.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:29:54
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Dec 2020 16:41:57
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 20:29:45

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Dec 2020 16:41:57
User entered '0'	System	06 Nov 2020 20:29:45

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:10:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:29:45

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:10:59

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:00:15
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: 09 Jun 2021 16:10:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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)	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)	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)	14 Aug 2020 20:24:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered empty.	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: 09 Jun 2021 16:10:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered empty.	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: 09 Jun 2021 16:10:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered empty.	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: 09 Jun 2021 16:10:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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 Mahoney (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: 09 Jun 2021 16:10:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered empty.	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: 09 Jun 2021 16:10:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered empty.	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: 09 Jun 2021 16:10:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered empty.	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: 09 Jun 2021 16:10:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered '100'	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: 09 Jun 2021 16:10:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered empty.	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: 09 Jun 2021 16:10:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered empty.	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: 09 Jun 2021 16:10:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered empty.	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: 09 Jun 2021 16:10:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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.' answered with 'data correct as is per source.' (Site from System).	Shannon Moyer (b) (4) (b) (4)	14 Aug 2020 20:29:26
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) (b) (4)	14 Aug 2020 20:26:09

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered empty.	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: 09 Jun 2021 16:10:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered empty.	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: 09 Jun 2021 16:10:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Oral (ORAL)'	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: 09 Jun 2021 16:10:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered empty.	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: 09 Jun 2021 16:10:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered empty.	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: 09 Jun 2021 16:10:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:37
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:10:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:37
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'No (N)'	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: 09 Jun 2021 16:10:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:37
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Headache'	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: 09 Jun 2021 16:10:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:37
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered '500'	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: 09 Jun 2021 16:10:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:37
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'mg (mg)'	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: 09 Jun 2021 16:10:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:37
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered empty.	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: 09 Jun 2021 16:10:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:37
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'once daily (QD)'	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: 09 Jun 2021 16:10:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:37
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered empty.	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: 09 Jun 2021 16:10:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:37
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Oral (ORAL)'	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: 09 Jun 2021 16:10:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:37
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered empty.	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: 09 Jun 2021 16:10:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:37
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered '12 Sep 2020'	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: 09 Jun 2021 16:10:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:37
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered '0'	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: 09 Jun 2021 16:10:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:37
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'No (N)'	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: 09 Jun 2021 16:10:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:37
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered '13 Sep 2020'	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: 09 Jun 2021 16:10:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:37
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'No (N)'	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: 09 Jun 2021 16:10:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:37
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: 09 Jun 2021 16:10:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:37
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: 09 Jun 2021 16:10:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:37
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: 09 Jun 2021 16:10:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User closed query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. (13 days after dose 1). (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 13:47:54
Query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. (13 days after dose 1).' answered with 'Subject did not meet EC #9.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	04 Dec 2020 13:50:41
User opened query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. (13 days after dose 1). (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 15:39:54
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)	06 Nov 2020 18:06:18

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:10:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
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: 09 Jun 2021 16:10:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:49
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: 09 Jun 2021 16:10:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:49
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: 09 Jun 2021 16:10:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:04:49
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: 09 Jun 2021 16:10:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:04:44
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOETHYROXINE - 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)	06 Nov 2020 18:07:36

US3252166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:04:47
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: 09 Jun 2021 16:10:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:04:49
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: 09 Jun 2021 16:10:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:04:53
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: 09 Jun 2021 16:10:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:05:00
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: 09 Jun 2021 16:10:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:05:01
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: 09 Jun 2021 16:10:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:05:05
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: 09 Jun 2021 16:10:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:05:06
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: 09 Jun 2021 16:10:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:05:08
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: 09 Jun 2021 16:10:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:05:09
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: 09 Jun 2021 16:10:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:05:11
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: 09 Jun 2021 16:10:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:05:13
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: 09 Jun 2021 16:10:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:05:18
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: 09 Jun 2021 16:10:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:05:20
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: 09 Jun 2021 16:10:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:05:26
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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[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: 09 Jun 2021 16:10:59

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User closed query 'Per source, Thyroidectomy is listed as a concomitant procedure. Please add to the concomitant procedures log in EDC.' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 01:30:53
Query 'Per source, Thyroidectomy is listed as a concomitant procedure. Please add to the concomitant procedures log in EDC.' answered with 'updated information under concomitant procedure log line 6 ' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 09:45:00
User opened query 'Per source, Thyroidectomy is listed as a concomitant procedure. Please add to the concomitant procedures log in EDC.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 18:04:30
User closed query 'Per source, Thyroidectomy is listed as a concomitant procedures. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 15:33:45
Query 'Per source, Thyroidectomy is listed as a concomitant procedures. Please verify and update EDC accordingly.' answered with 'per source updated accordingly.' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	29 Jan 2021 07:59:04
User opened query 'Per source, Thyroidectomy is listed as a concomitant procedures. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 19:10:21
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:05:34
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: 09 Jun 2021 16:10:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:06:06
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: 09 Jun 2021 16:10:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:06:09
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: 09 Jun 2021 16:10:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:06:22
User closed query 'Per DM CLR - Requery: Response noted, however, indication remain DIAGNOSTIC. Please update indication to reflect what was noted in the response (AE). Reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 11:38:08
Query 'Per DM CLR - Requery: Response noted, however, indication remain DIAGNOSTIC. Please update indication to reflect what was noted in the response (AE). Reconcile and update as appropriate, otherwise clarify.' answered with 'updated.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	05 Dec 2020 16:56:47
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	05 Dec 2020 16:56:41
User opened query 'Per DM CLR - Requery: Response noted, however, indication remain DIAGNOSTIC. Please update indication to reflect what was noted in the response (AE). Reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 09:32:05
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

US3252166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:10:59

[Indication](#)

Audit	User	Time (GMT)
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.'	Uche Ehiemua (b) (4)	06 Nov 2020 20:16:40
answered with 'Procedure was done for an AE condition, updated in AE eCRF' (Site from DM).	(b) (4)	
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Uche Ehiemua (b) (4)	06 Nov 2020 20:16:33
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4)	
User entered 'Medical History (MH)' reason for change: Data Entry Error	Joanna Gurrola Mahoney	05 Nov 2020 20:53:07
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)	
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	01 Nov 2020 04:36:59
	(b) (4), (b) (6)	01 Oct 2020 16:45:46

US3252166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:10:59

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:06:30
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 16:45:46

US3252166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:10:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:25:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered '30 Oct 2020'	(b) (4), (b) (6)	11 Feb 2021 09:44:26

US3252166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:10:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:25:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'thyroidectomy'	(b) (4), (b) (6)	11 Feb 2021 09:44:26

US3252166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:10:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:25:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	11 Feb 2021 09:44:26

US3252166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:10:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:25:14
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 09:44:26

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'USA-US108-2020-MRNA-1273-P301000019'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Yes (Y)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Yes (Y)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Joel'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Solis'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:48:55
Un-reviewed for Safety.	System	13 Apr 2021 18:01:06
Signature has been broken.	System	13 Apr 2021 18:01:06
User entered '5201 N. 10th Street'	System	13 Apr 2021 18:01:06
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:00:56
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	02 Apr 2021 19:52:34
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:06:33
User closed query 'Please update to the correct site address.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 21:06:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
Un-reviewed for Safety.	System	25 Feb 2021 17:58:22
User entered '5201 N. 10th Street'	System	25 Feb 2021 17:58:22
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:58:04
Un-reviewed for Safety.	Joanna Gurrola Mahoney (b) (4)	24 Feb 2021 20:18:44
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	24 Feb 2021 20:18:44
Data Entry Error	(b) (4)	
Query 'Please update to the correct site address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 04:01:49
User opened query 'Please update to the correct site address.' (Site from CRA).		27 Jan 2021 18:59:44
DataPoint Un-verified.		27 Jan 2021 18:59:17
DataPoint Verified.		08 Jan 2021 05:27:12
Reviewed for Safety.		06 Dec 2020 17:26:59
User entered '5201 N. 10th Street'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Mcallen'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'TX'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:48:55
Un-reviewed for Safety.	System	13 Apr 2021 18:01:06
Signature has been broken.	System	13 Apr 2021 18:01:06
User entered 'carmpa'	System	13 Apr 2021 18:01:06
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:00:56
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:06:32
User closed query 'Please update to the correct site zip code.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 21:06:29
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
Un-reviewed for Safety.	System	25 Feb 2021 17:58:22
User entered 'carmpa'	System	25 Feb 2021 17:58:22
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:58:04
Query 'Please update to the correct site zip code.' answered with 'updated' (Site from CRA).		24 Feb 2021 04:01:52
Un-reviewed for Safety.		24 Feb 2021 04:01:38
User entered '78504' reason for change: Data Entry Error		24 Feb 2021 04:01:38
User opened query 'Please update to the correct site zip code.' (Site from CRA).		27 Jan 2021 18:59:30
DataPoint Un-verified.		27 Jan 2021 18:59:19
DataPoint Verified.		08 Jan 2021 05:27:12
Reviewed for Safety.		06 Dec 2020 17:26:59
User entered 'carmpa'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 15:47:13
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
User entered 'US'	System	06 Dec 2020 17:27:07

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	13 Apr 2021 18:01:06
User entered '3'	System	25 Feb 2021 17:58:22
User entered '2'	System	12 Feb 2021 15:47:34
User entered '1'	System	06 Dec 2020 17:27:07

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'USA-US108-2020-MRNA-1273-P301000019'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Yes (Y)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Yes (Y)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Joel'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Solis'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:48:55
Un-reviewed for Safety.	System	13 Apr 2021 18:01:06
Signature has been broken.	System	13 Apr 2021 18:01:06
User entered '5201 N. 10th Street'	System	13 Apr 2021 18:01:06
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:00:56
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	02 Apr 2021 19:52:34
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:06:33
User closed query 'Please update to the correct site address.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 21:06:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
Un-reviewed for Safety.	System	25 Feb 2021 17:58:22
User entered '5201 N. 10th Street'	System	25 Feb 2021 17:58:22
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:58:04
Un-reviewed for Safety.	Joanna Gurrola Mahoney (b) (4)	24 Feb 2021 20:18:44
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	24 Feb 2021 20:18:44
Data Entry Error	(b) (4)	
Query 'Please update to the correct site address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 04:01:49
User opened query 'Please update to the correct site address.' (Site from CRA).		27 Jan 2021 18:59:44
DataPoint Un-verified.		27 Jan 2021 18:59:17
DataPoint Verified.		08 Jan 2021 05:27:12
Reviewed for Safety.		06 Dec 2020 17:26:59
User entered '5201 N. 10th Street'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Mcallen'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'TX'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:48:55
Un-reviewed for Safety.	System	13 Apr 2021 18:01:06
Signature has been broken.	System	13 Apr 2021 18:01:06
User entered 'carmpa'	System	13 Apr 2021 18:01:06
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:00:56
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:06:32
User closed query 'Please update to the correct site zip code.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 21:06:29
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
Un-reviewed for Safety.	System	25 Feb 2021 17:58:22
User entered 'carmpa'	System	25 Feb 2021 17:58:22
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:58:04
Query 'Please update to the correct site zip code.' answered with 'updated' (Site from CRA).		24 Feb 2021 04:01:52
Un-reviewed for Safety.		24 Feb 2021 04:01:38
User entered '78504' reason for change: Data Entry Error		24 Feb 2021 04:01:38
User opened query 'Please update to the correct site zip code.' (Site from CRA).		27 Jan 2021 18:59:30
DataPoint Un-verified.		27 Jan 2021 18:59:19
DataPoint Verified.		08 Jan 2021 05:27:12
Reviewed for Safety.		06 Dec 2020 17:26:59
User entered 'carmpa'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 15:47:13
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
User entered 'US'	System	06 Dec 2020 17:27:07

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	13 Apr 2021 18:01:06
User entered '3'	System	25 Feb 2021 17:58:22
User entered '2'	System	12 Feb 2021 15:47:34
User entered '1'	System	06 Dec 2020 17:27:07

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:10:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
User entered '06/Dec/2020 17:27'	System	06 Dec 2020 17:27:07

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:10:59

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 signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 15:47:13
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
User entered '1'	(b) (4), (b) (6)	06 Dec 2020 17:27:07

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'USA-US108-2020-MRNA-1273-P301000019'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Yes (Y)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Yes (Y)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Joel'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Solis'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:48:55
Un-reviewed for Safety.	System	13 Apr 2021 18:01:06
Signature has been broken.	System	13 Apr 2021 18:01:06
User entered '5201 N. 10th Street'	System	13 Apr 2021 18:01:06
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:00:56
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	02 Apr 2021 19:52:34
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:06:33
User closed query 'Please update to the correct site address.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 21:06:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
Un-reviewed for Safety.	System	25 Feb 2021 17:58:22
User entered '5201 N. 10th Street'	System	25 Feb 2021 17:58:22
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:58:04
Un-reviewed for Safety.	Joanna Gurrola Mahoney (b) (4)	24 Feb 2021 20:18:44
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	24 Feb 2021 20:18:44
Data Entry Error	(b) (4)	
Query 'Please update to the correct site address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 04:01:49
User opened query 'Please update to the correct site address.' (Site from CRA).		27 Jan 2021 18:59:44
DataPoint Un-verified.		27 Jan 2021 18:59:17
DataPoint Verified.		08 Jan 2021 05:27:12
Reviewed for Safety.		06 Dec 2020 17:26:59
User entered '5201 N. 10th Street'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Mcallen'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'TX'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:48:55
Un-reviewed for Safety.	System	13 Apr 2021 18:01:06
Signature has been broken.	System	13 Apr 2021 18:01:06
User entered 'carmpa'	System	13 Apr 2021 18:01:06
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:00:56
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:06:32
User closed query 'Please update to the correct site zip code.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 21:06:29
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
Un-reviewed for Safety.	System	25 Feb 2021 17:58:22
User entered 'carmpa'	System	25 Feb 2021 17:58:22
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:58:04
Query 'Please update to the correct site zip code.' answered with 'updated' (Site from CRA).		24 Feb 2021 04:01:52
Un-reviewed for Safety.		24 Feb 2021 04:01:38
User entered '78504' reason for change: Data Entry Error		24 Feb 2021 04:01:38
User opened query 'Please update to the correct site zip code.' (Site from CRA).		27 Jan 2021 18:59:30
DataPoint Un-verified.		27 Jan 2021 18:59:19
DataPoint Verified.		08 Jan 2021 05:27:12
Reviewed for Safety.		06 Dec 2020 17:26:59
User entered 'carmpa'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 15:47:13
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
User entered 'US'	System	06 Dec 2020 17:27:07

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	13 Apr 2021 18:01:06
User entered '3'	System	25 Feb 2021 17:58:22
User entered '2'	System	12 Feb 2021 15:47:34
User entered '1'	System	06 Dec 2020 17:27:07

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:10:59

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered '12/Feb/2021 10:47'	System	12 Feb 2021 15:47:34

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:10:59

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 signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:58:04
User entered 'I'	(b) (4), (b) (6)	12 Feb 2021 15:47:34

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'USA-US108-2020-MRNA-1273-P301000019'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Yes (Y)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Yes (Y)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Joel'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Solis'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:48:55
Un-reviewed for Safety.	System	13 Apr 2021 18:01:06
Signature has been broken.	System	13 Apr 2021 18:01:06
User entered '5201 N. 10th Street'	System	13 Apr 2021 18:01:06
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:00:56
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	02 Apr 2021 19:52:34
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:06:33
User closed query 'Please update to the correct site address.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 21:06:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
Un-reviewed for Safety.	System	25 Feb 2021 17:58:22
User entered '5201 N. 10th Street'	System	25 Feb 2021 17:58:22
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:58:04
Un-reviewed for Safety.	Joanna Gurrola Mahoney (b) (4)	24 Feb 2021 20:18:44
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	24 Feb 2021 20:18:44
Data Entry Error	(b) (4)	
Query 'Please update to the correct site address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 04:01:49
User opened query 'Please update to the correct site address.' (Site from CRA).		27 Jan 2021 18:59:44
DataPoint Un-verified.		27 Jan 2021 18:59:17
DataPoint Verified.		08 Jan 2021 05:27:12
Reviewed for Safety.		06 Dec 2020 17:26:59
User entered '5201 N. 10th Street'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Mcallen'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'TX'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:48:55
Un-reviewed for Safety.	System	13 Apr 2021 18:01:06
Signature has been broken.	System	13 Apr 2021 18:01:06
User entered 'carmpa'	System	13 Apr 2021 18:01:06
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:00:56
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:06:32
User closed query 'Please update to the correct site zip code.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 21:06:29
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
Un-reviewed for Safety.	System	25 Feb 2021 17:58:22
User entered 'carmpa'	System	25 Feb 2021 17:58:22
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:58:04
Query 'Please update to the correct site zip code.' answered with 'updated' (Site from CRA).		24 Feb 2021 04:01:52
Un-reviewed for Safety.		24 Feb 2021 04:01:38
User entered '78504' reason for change: Data Entry Error		24 Feb 2021 04:01:38
User opened query 'Please update to the correct site zip code.' (Site from CRA).		27 Jan 2021 18:59:30
DataPoint Un-verified.		27 Jan 2021 18:59:19
DataPoint Verified.		08 Jan 2021 05:27:12
Reviewed for Safety.		06 Dec 2020 17:26:59
User entered 'carmpa'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 15:47:13
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
User entered 'US'	System	06 Dec 2020 17:27:07

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	13 Apr 2021 18:01:06
User entered '3'	System	25 Feb 2021 17:58:22
User entered '2'	System	12 Feb 2021 15:47:34
User entered '1'	System	06 Dec 2020 17:27:07

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:10:59

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered '25/Feb/2021 11:58'	System	25 Feb 2021 17:58:22

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:10:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:00:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
User entered 'I'	(b) (4), (b) (6)	25 Feb 2021 17:58:22

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'USA-US108-2020-MRNA-1273-P301000019'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Yes (Y)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Yes (Y)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

US3252166

Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

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Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'No (N)'	System	06 Dec 2020 17:24:59

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Joel'	System	06 Dec 2020 17:24:59

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Solis'	System	06 Dec 2020 17:24:59

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Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

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Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:48:55
Un-reviewed for Safety.	System	13 Apr 2021 18:01:06
Signature has been broken.	System	13 Apr 2021 18:01:06
User entered '5201 N. 10th Street'	System	13 Apr 2021 18:01:06
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:00:56
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	02 Apr 2021 19:52:34
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:06:33
User closed query 'Please update to the correct site address.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 21:06:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
Un-reviewed for Safety.	System	25 Feb 2021 17:58:22
User entered '5201 N. 10th Street'	System	25 Feb 2021 17:58:22
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:58:04
Un-reviewed for Safety.	Joanna Gurrola Mahoney (b) (4)	24 Feb 2021 20:18:44
User entered '1020 Zinnia Ave' reason for change:	Joanna Gurrola Mahoney	24 Feb 2021 20:18:44
Data Entry Error	(b) (4)	
Query 'Please update to the correct site address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 04:01:49
User opened query 'Please update to the correct site address.' (Site from CRA).		27 Jan 2021 18:59:44
DataPoint Un-verified.		27 Jan 2021 18:59:17
DataPoint Verified.		08 Jan 2021 05:27:12
Reviewed for Safety.		06 Dec 2020 17:26:59
User entered '5201 N. 10th Street'	System	06 Dec 2020 17:24:59

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Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'Mcallen'	System	06 Dec 2020 17:24:59

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Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:26:59
User entered 'TX'	System	06 Dec 2020 17:24:59

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Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form

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Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:48:55
Un-reviewed for Safety.	System	13 Apr 2021 18:01:06
Signature has been broken.	System	13 Apr 2021 18:01:06
User entered 'carmpa'	System	13 Apr 2021 18:01:06
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:00:56
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:51:17
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	02 Apr 2021 19:52:34
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:06:32
User closed query 'Please update to the correct site zip code.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 21:06:29
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
Un-reviewed for Safety.	System	25 Feb 2021 17:58:22
User entered 'carmpa'	System	25 Feb 2021 17:58:22
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:58:04
Query 'Please update to the correct site zip code.' answered with 'updated' (Site from CRA).		24 Feb 2021 04:01:52
Un-reviewed for Safety.		24 Feb 2021 04:01:38
User entered '78504' reason for change: Data Entry Error		24 Feb 2021 04:01:38
User opened query 'Please update to the correct site zip code.' (Site from CRA).		27 Jan 2021 18:59:30
DataPoint Un-verified.		27 Jan 2021 18:59:19
DataPoint Verified.		08 Jan 2021 05:27:12
Reviewed for Safety.		06 Dec 2020 17:26:59
User entered 'carmpa'	System	06 Dec 2020 17:24:59

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:17:16
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 15:47:13
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:27:12
User entered 'US'	System	06 Dec 2020 17:27:07

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	13 Apr 2021 18:01:06
User entered '3'	System	25 Feb 2021 17:58:22
User entered '2'	System	12 Feb 2021 15:47:34
User entered '1'	System	06 Dec 2020 17:27:07

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Form: Safety Report Form (4)

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Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:48:55
User entered '13/Apr/2021 13:01'	System	13 Apr 2021 18:01:06

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Folder: SAE USA-US108-2020-MRNA-1273-P301000019

Form: Safety Report Form (4)

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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 signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:48:55
User entered '1'	(b) (4), (b) (6)	13 Apr 2021 18:01:06