

US3252399 (Prod: Centex Studies Inc)

Generated By: KC Joubran

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US3252399

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 20:38:01

Generated On: 09 Jun 2021 16:14:00

[Participant ID](#)

US3252399

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

US3252399

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3252399

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Date of Birth (MMM yyyy)	(b) (6) 1973
Age	47
Age Units	YEARS
Age (Derived)	47
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 02:18:06

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

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 02:18:06

Generated On: 09 Jun 2021 16:14:00

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN JAN 2013
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 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Condition	LASIK
Start date (dd MMM yyyy)	UN MAR 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 MAR 2017
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2017
Start Year (derived)	2017
Stop Month and Year (derived)	MAR 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Condition	MYOPIA
Start date (dd MMM yyyy)	UN MAR 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 MAR 2017
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2017
Start Year (derived)	2017
Stop Month and Year (derived)	MAR 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Condition	POLYCYSTIC OVARY SYNDROME
Start date (dd MMM yyyy)	UN JAN 2013
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 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

US3252399

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	01 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	07:47 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 07:47
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	179 lb
BMI (<i>xxx.x</i>)	29.84944 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 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 02:18:06

Generated On: 09 Jun 2021 16:14:00

Date of assessment (*dd MMM yyyy*) 01 SEP 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 2013

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 02:18:06

Generated On: 09 Jun 2021 16:14:00

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 02:18:06

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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)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

What was the date of randomization? (dd MMM yyyy) 01 SEP 2020

What was the participant's randomization number? 110156

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 02:18:06

Generated On: 09 Jun 2021 16:14:00

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 02:18:06

Generated On: 09 Jun 2021 16:14:00

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	07:47 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 07:47
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	09:15 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 09:15
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

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 02:18:06

Generated On: 09 Jun 2021 16:14:00

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) 1 SEP 2020

What was the treatment time? (00:00-23:59) 08:39 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 08:39

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 02:18:06

Generated On: 09 Jun 2021 16:14:00

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	01 SEP 2020
Collection time (<i>00:00-23:59</i>)	08:27 (24 HR)
Collection date and time (derived)	01 SEP 2020 08:27

US3252399

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Collection date (dd MMM yyyy)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:18	01 SEP 2020 08:18
Nasopharyngeal Swab 2	No		

US3252399

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

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

01 SEP 2020 09:19

PC Open Date & Time

01 SEP 2020 08:59

PC Close Date & Time

01 SEP 2020 11:29

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

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 96.8 °F

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

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

PC Time Stamp	02 SEP 2020 10:48
PC Open Date & Time	01 SEP 2020 12:24
PC Close Date & Time	02 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:00

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 11:56

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:00

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

98.3 °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

04 SEP 2020 11:07

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

05 SEP 2020 09:53

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:00

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

94.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 11:39

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 11:37

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 09:19

PC Open Date & Time

01 SEP 2020 08:59

PC Close Date & Time

01 SEP 2020 11:29

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 10:49

PC Open Date & Time

01 SEP 2020 12:24

PC Close Date & Time

02 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 11:57

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 11:08

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 09:53

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 11:40

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 11:37

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

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 ☐

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 09:20
PC Open Date & Time	01 SEP 2020 08:59
PC Close Date & Time	01 SEP 2020 11:29

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

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 ☐

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 10:50
PC Open Date & Time	01 SEP 2020 12:24
PC Close Date & Time	02 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

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 ☒

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 11:57
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

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 ☒

PRODUCTION RELEASE (v12.003

49 of 2028

EAB) (1725)

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 11:08
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

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 ☒

PRODUCTION RELEASE (v12.003

51 of 2028

EAB) (1725)

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 09:53
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

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 ☒

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 11:40
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

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 ☐

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

Yes ☐

PC Time stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

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 ☒

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 11:38
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3252399

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252399

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252399

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 02:18:04

Generated On: 09 Jun 2021 16:14:00

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252399

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 02:18:04

Generated On: 09 Jun 2021 16:14:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252399

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 02:18:04

Generated On: 09 Jun 2021 16:14:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252399

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 02:18:04

Generated On: 09 Jun 2021 16:14:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252399

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	07:20 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 07:20
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	08:56 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 08:56
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3252399

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

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.

US3252399

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

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) 28 SEP 2020

What was the treatment time? (00:00-23:59) 08:26 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 08:26

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

US3252399

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 SEP 2020
Collection time (00:00-23:59)	07:42 (24 HR)
Collection date and time (derived)	28 SEP 2020 07:42

US3252399

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:30	28 SEP 2020 07:30
Nasopharyngeal Swab 2	No		

US3252399

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

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

97.2 °F

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

Yes ☐
No ☒

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

PC Time Stamp 28 SEP 2020 09:00

PC Open Date & Time 28 SEP 2020 08:46

PC Close Date & Time 28 SEP 2020 11:16

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

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

97.7 °F

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

Yes ☐
No ☒

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

PC Time Stamp	28 SEP 2020 19:33
PC Open Date & Time	28 SEP 2020 12:11
PC Close Date & Time	29 SEP 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:00

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

98.0 °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

29 SEP 2020 23:46

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:00

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 06:49

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:00

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 21:07

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:00

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 19:39

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 10:29

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 22:09

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 09:01

PC Open Date & Time

28 SEP 2020 08:46

PC Close Date & Time

28 SEP 2020 11:16

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

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

28 SEP 2020 19:34

PC Open Date & Time

28 SEP 2020 12:11

PC Close Date & Time

29 SEP 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 23:47

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 06:50

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 21:07

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 19:39

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 10:29

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 22:09

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

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 ☐

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 09:01
PC Open Date & Time	28 SEP 2020 08:46
PC Close Date & Time	28 SEP 2020 11:16

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

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 ☐

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 19:35
PC Open Date & Time	28 SEP 2020 12:11
PC Close Date & Time	29 SEP 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

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 ☒

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 23:47
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

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 ☒

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 06:50
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

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 ☒

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 21:08
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

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 ☒

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 19:40
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

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 ☒

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 10:29
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

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 ☒

PRODUCTION RELEASE (v12.003

103 of 2028

EAB) (1725)

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 22:09
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3252399

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 02:18:04

Generated On: 09 Jun 2021 16:14:00

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 OCT 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252399

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 02:18:04

Generated On: 09 Jun 2021 16:14:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252399

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252399

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252399

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252399

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 02:18:06

Generated On: 09 Jun 2021 16:14:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252399

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 02:18:07

Generated On: 09 Jun 2021 16:14:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3252399

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 02:18:07

Generated On: 09 Jun 2021 16:14:00

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	08:35 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 08:35
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>)	87 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 02:18:07

Generated On: 09 Jun 2021 16:14:00

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.

US3252399

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 02:18:07

Generated On: 09 Jun 2021 16:14:00

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 OCT 2020
Collection time (00:00-23:59)	08:41 (24 HR)
Collection date and time (derived)	30 OCT 2020 08:41

US3252399

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 02:18:07

Generated On: 09 Jun 2021 16:14:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 NOV 2020 18:06:03

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 18:01:59

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

16 NOV 2020 08:21:32

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	23 NOV 2020 11:18:44
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 12:42:20

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	07 DEC 2020 17:57:35
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 103

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

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

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

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

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

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

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

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

20 DEC 2020 07:25:11

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

28 DEC 2020 07:42:42

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 18:54:21

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 07:45:31

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

17 JAN 2021 01:33:49

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 17:25:38

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

30 JAN 2021 12:00:33

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 19:18:49

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 13:16:56
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

21 FEB 2021 08:59:20

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 FEB 2021 16:43:11

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 15:08:16

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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 MAR 2021 16:40:22
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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	19 MAR 2021 15:26:02
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 23:01:05

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 12:33:25

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 14:45:57

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 12:01:19

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 18:03:20

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 11:09:42

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

Date and time of submission	
Patient Cloud Open Date & Time	03 JUN 2021 00:01
Patient Cloud Close Date & Time	07 JUN 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 327

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

Patient Cloud Open Date & Time	12 AUG 2021 00:01
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Patient Cloud Close Date & Time	16 AUG 2021 23:59
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US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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 ☐

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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 ☐

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2021 00:01
Patient Cloud Close Date & Time	11 OCT 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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 ☐

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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 ☐

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 FEB 2022 00:01
Patient Cloud Close Date & Time	21 FEB 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 FEB 2022 00:01
Patient Cloud Close Date & Time	28 FEB 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 MAR 2022 00:01
Patient Cloud Close Date & Time	14 MAR 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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 ☐

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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 ☐

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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 ☐

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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 ☐

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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 ☐

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

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 ☐

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

Patient Cloud Open Date & Time	11 AUG 2022 00:01
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Patient Cloud Close Date & Time	15 AUG 2022 23:59
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US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

Patient Cloud Open Date & Time	18 AUG 2022 00:01
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Patient Cloud Close Date & Time	22 AUG 2022 23:59
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US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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 ☐

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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 ☐

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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 ☐

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2022 00:01
Patient Cloud Close Date & Time	31 OCT 2022 23:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3252399

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:14:00

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		27 FEB 2021 16:42:46

US3252399

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 NOV 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252399

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252399

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252399

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252399

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252399

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252399

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252399

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252399

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 20:11:40

Generated On: 09 Jun 2021 16:14:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3252399

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 20:11:40

Generated On: 09 Jun 2021 16:14:00

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) _____

US3252399

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 20:11:40

Generated On: 09 Jun 2021 16:14:00

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.

US3252399

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 20:11:40

Generated On: 09 Jun 2021 16:14:00

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 MAR 2021
Collection time (00:00-23:59)	07:44 (24 HR)
Collection date and time (derived)	26 MAR 2021 07:44

US3252399

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:11:40

Generated On: 09 Jun 2021 16:14:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252399

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3252399

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:14:00

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3252399

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	22 JAN 2021
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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
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US3252399

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 20:11:38

Generated On: 09 Jun 2021 16:14:00

Date of updated informed consent (<i>dd MMM yyyy</i>)	22 JAN 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>)	22 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3252399

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3252399

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	07:32 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 07:32
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3252399

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	08:41 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 08:41
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3252399

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

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

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.

US3252399

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

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 22 JAN 2021

What was the treatment time? (00:00-23:59) 08:03 (24 HR)

Treatment Date and Time (derived) 22 JAN 2021 08:03

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

US3252399

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	22 JAN 2021
Collection time (<i>00:00-23:59</i>)	07:45 (24 HR)
Collection date and time (derived)	22 JAN 2021 07:45

US3252399

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	07:45
Collection Date and Time (derived)	22 JAN 2021 07:45

US3252399

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

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252399

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252399

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3252399

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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	OLD29

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	09:54 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 09:54
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 10:55
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3252399

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

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.

US3252399

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 FEB 2021

What was the treatment time? (00:00-23:59) 10:19 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 10:19

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

US3252399

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252399

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:11:40

Generated On: 09 Jun 2021 16:14:00

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 MAR 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252399

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:11:40

Generated On: 09 Jun 2021 16:14:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252399

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 20:11:37

Generated On: 09 Jun 2021 16:14:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3252399

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 20:11:37

Generated On: 09 Jun 2021 16:14:00

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	07:31 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 07:31
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>)	92 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252399

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 20:11:37

Generated On: 09 Jun 2021 16:14:00

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.

US3252399

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 18:58:52

Generated On: 09 Jun 2021 16:14:00

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	26 MAR 2021
Collection time (<i>00:00-23:59</i>)	07:45 (24 HR)
Collection date and time (derived)	26 MAR 2021 07:45

US3252399

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Apr 2021 20:11:37

Generated On: 09 Jun 2021 16:14:00

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3252399

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 11:42:42

Generated On: 09 Jun 2021 16:14:00

AEID	USA-US108-2021-MRNA-1273-P30 1000016
Adverse event	CERVICAL DYSPLASIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	8 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	9 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	8 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	9 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 11:42:42

Generated On: 09 Jun 2021 16:14:00

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 <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	THE PATIENT UNDERWENT SURGERY TO HAVE HER CERVIX REMOVED DUE TO CERVICAL DYSPLASIA, THE PATIENT IS STABLE. TRACHELECTOMY WAS PERFORMED.

US3252399

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 11:42:42

Generated On: 09 Jun 2021 16:14:00

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 11:42:42

Generated On: 09 Jun 2021 16:14:00

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	17 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 11:42:42

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 11:42:42

Generated On: 09 Jun 2021 16:14:00

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 11:42:42

Generated On: 09 Jun 2021 16:14:00

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 11:42:42

Generated On: 09 Jun 2021 16:14:00

AEID

Adverse event

MUSCLE ACHES

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)

17 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)

21 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

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 11:42:42

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 20:38:02

Generated On: 09 Jun 2021 16:14:00

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

Yes ☒

No ☐

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

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 20:38:01

Generated On: 09 Jun 2021 16:14:00

Name of Medication VITAMIN C SUPPLEMENT

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

Dose per administration 1000

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 20:38:01

Generated On: 09 Jun 2021 16:14:00

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 20:38:01

Generated On: 09 Jun 2021 16:14:00

Name of Medication ZINC SUPPLEMENT

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

Dose per administration 15

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 20:38:01

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 20:38:01

Generated On: 09 Jun 2021 16:14:00

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 81

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 20:38:01

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 20:11:37

Generated On: 09 Jun 2021 16:14:00

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3252399

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 06 Apr 2021 22:27:04

Generated On: 09 Jun 2021 16:14:00

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
08 MAR 2021	TRACHELECTOMY SURGERY	Adverse Event	

US3252399

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:14:00

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

US3252399

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:14:00

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 ☐

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 11:42:43

Generated On: 09 Jun 2021 16:14:00

SAEID	USA-US108-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 11:42:43

Generated On: 09 Jun 2021 16:14:00

SAEID	USA-US108-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	29/MAR/2021 11:47
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.	True

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 11:42:43

Generated On: 09 Jun 2021 16:14:00

SAEID	USA-US108-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	07/APR/2021 13:10
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

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 11:42:43

Generated On: 09 Jun 2021 16:14:00

SAEID	USA-US108-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	26/APR/2021 09:17
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

US3252399 (Prod: Centex Studies Inc)

US3252399

Form: Participant Creation

Generated On: 09 Jun 2021 16:14:00

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'US3252399'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:15:08

US3252399

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	02 Sep 2020 13:59:05
	(b) (4)	

US3252399

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:15:09

US3252399

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[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 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4)	02 Sep 2020 13:59:05
	(b) (4)	

US3252399

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'SCRN'	System	02 Sep 2020 13:59:05

US3252399

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:00

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered (b) (6) 1973'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:15:10

US3252399

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:00

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '47'	Shannon Moyer (b) (4)	02 Sep 2020 13:59:22
	(b) (4)	

US3252399

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:00

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'YEARS'	System	02 Sep 2020 13:59:22

US3252399

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:00

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '47'	System	01 Sep 2020 13:43:06

US3252399

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:00

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Female (F)'	Shannon Moyer (b) (4)	02 Sep 2020 13:59:22
	(b) (4)	

US3252399

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:00

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Shannon Moyer (b) (4)	02 Sep 2020 13:59:22
	(b) (4)	

US3252399

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:00

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'I'	Shannon Moyer (b) (4)	02 Sep 2020 13:59:22
	(b) (4)	

US3252399

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:00

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 13:59:22
	(b) (4)	

US3252399

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:00

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 13:59:22
	(b) (4)	

US3252399

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:00

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 13:59:22
	(b) (4)	

US3252399

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:00

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 13:59:22
	(b) (4)	

US3252399

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:00

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 13:59:22
	(b) (4)	

US3252399

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:00

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 13:59:22
	(b) (4)	

US3252399

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:00

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 13:59:22
	(b) (4)	

US3252399

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:00

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 13:59:22
	(b) (4)	

US3252399

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:00

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '1 Sep 2020'	Xavier Morales (b) (4)	01 Sep 2020 13:43:06
	(b) (4)	

US3252399

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'Sep 2020'	System	01 Sep 2020 13:43:06

US3252399

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '2020'	System	01 Sep 2020 13:43:06

US3252399

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:00

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Amendment 3 (3)'	Xavier Morales (b) (4)	01 Sep 2020 13:43:06
	(b) (4)	

US3252399

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Xavier Morales (b) (4)	01 Sep 2020 13:43:06
	(b) (4)	

US3252399

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:00

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Xavier Morales (b) (4)	01 Sep 2020 13:43:06
	(b) (4)	

US3252399

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:00

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Xavier Morales (b) (4)	01 Sep 2020 13:43:06
	(b) (4)	

US3252399

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:00

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	02 Sep 2020 13:59:40
User entered 'Yes (Y)'	Xavier Morales (b) (4)	01 Sep 2020 13:43:06

US3252399

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:00

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	02 Sep 2020 13:59:40
User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	01 Sep 2020 13:43:06
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:15:09

US3252399

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:00

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'I'	System	01 Sep 2020 13:43:13

US3252399

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Xavier Morales (b) (4)	01 Sep 2020 13:43:13
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:14:00

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	02 Sep 2020 14:00:03
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:00

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Prediabetes - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 14:01:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	02 Sep 2020 14:00:38
User entered 'Prediabetes'	Shannon Moyer (b) (4)	02 Sep 2020 14:00:38
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'UN UNK 2019'	Shannon Moyer (b) (4)	02 Sep 2020 14:00:38
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 14:00:38
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	02 Sep 2020 14:00:38
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:00:38
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 14:00:38
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'Jan 2019'	System	02 Sep 2020 14:00:38

US3252399

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '2019'	System	02 Sep 2020 14:00:38

US3252399

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered empty.	System	02 Sep 2020 14:00:38

US3252399

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered empty.	System	02 Sep 2020 14:00:38

US3252399

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:00

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:45:24
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 'UPDATED' (Site from DM).	Xavier Morales (b) (4)	21 Oct 2020 17:26:53
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)	15 Oct 2020 19:00:50
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)	02 Sep 2020 14:02:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 14:02:50
Data point term sent to Coder	System	02 Sep 2020 14:01:39
User entered 'Hysterectomy'	Shannon Moyer (b) (4)	02 Sep 2020 14:01:17

US3252399

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'UN Jan 2013'	Shannon Moyer (b) (4)	02 Sep 2020 14:01:17
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 14:01:17
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:01:17
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'UN Jan 2013'	Shannon Moyer (b) (4)	02 Sep 2020 14:01:17
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 14:01:17
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'Jan 2013'	System	02 Sep 2020 14:01:17

US3252399

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '2013'	System	02 Sep 2020 14:01:17

US3252399

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'Jan 2013'	System	02 Sep 2020 14:01:17

US3252399

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '2013'	System	02 Sep 2020 14:01:17

US3252399

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:45:24
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 'UPDATED' (Site from DM).	Xavier Morales (b) (4)	21 Oct 2020 17:27:04
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)	15 Oct 2020 19:01:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Keratomileusis, LLT: LASIK eye surgery - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 14:03:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	02 Sep 2020 14:03:40
Data point term sent to Coder	System	02 Sep 2020 14:02:41
User entered 'Lasik'	Shannon Moyer (b) (4)	02 Sep 2020 14:01:42

US3252399

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'UN Mar 2017'	Shannon Moyer (b) (4)	02 Sep 2020 14:01:42
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 14:01:42
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	02 Sep 2020 14:01:58
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	02 Sep 2020 14:01:58
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 14:01:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 14:01:48
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	02 Sep 2020 14:01:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	02 Sep 2020 14:01:48
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 14:01:42
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:01:42

US3252399

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'UN Mar 2017'	Shannon Moyer (b) (4)	02 Sep 2020 14:01:42
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 14:01:42
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'Mar 2017'	System	02 Sep 2020 14:01:42

US3252399

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '2017'	System	02 Sep 2020 14:01:42

US3252399

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'Mar 2017'	System	02 Sep 2020 14:01:42

US3252399

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '2017'	System	02 Sep 2020 14:01:42

US3252399

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:00

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User coded data point as SOC: Eye disorders, HLGT: Coder Import Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	(b) (4)	21 Oct 2020 17:27:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:27:41
Data point term sent to Coder	(b) (4)	21 Oct 2020 17:26:35
User entered 'MYOPIA'	System	21 Oct 2020 17:26:35
	Xavier Morales (b) (4)	21 Oct 2020 17:25:53
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'UN Mar 2017'	Xavier Morales (b) (4)	21 Oct 2020 17:25:53
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Xavier Morales (b) (4)	21 Oct 2020 17:25:53
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Xavier Morales (b) (4)	21 Oct 2020 17:25:53
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'UN Mar 2017'	Xavier Morales (b) (4)	21 Oct 2020 17:25:53
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Xavier Morales (b) (4)	21 Oct 2020 17:25:53
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'Mar 2017'	System	21 Oct 2020 17:25:53

US3252399

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '2017'	System	21 Oct 2020 17:25:53

US3252399

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'Mar 2017'	System	21 Oct 2020 17:25:53

US3252399

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '2017'	System	21 Oct 2020 17:25:53

US3252399

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:00

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Polycystic ovaries, LLT: Polycystic ovarian syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:27:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:27:40
Data point term sent to Coder	System	21 Oct 2020 17:26:37
User entered 'Polycystic ovary syndrome'	Xavier Morales (b) (4)	21 Oct 2020 17:26:33
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'UN Jan 2013'	Xavier Morales (b) (4)	21 Oct 2020 17:26:33
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Xavier Morales (b) (4)	21 Oct 2020 17:26:33
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Xavier Morales (b) (4)	21 Oct 2020 17:26:33
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'UN Jan 2013'	Xavier Morales (b) (4)	21 Oct 2020 17:26:33
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Xavier Morales (b) (4)	21 Oct 2020 17:26:33
	(b) (4)	

US3252399

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'Jan 2013'	System	21 Oct 2020 17:26:33

US3252399

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '2013'	System	21 Oct 2020 17:26:33

US3252399

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'Jan 2013'	System	21 Oct 2020 17:26:33

US3252399

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '2013'	System	21 Oct 2020 17:26:33

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	02 Sep 2020 14:02:40
	(b) (4)	

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '01 Sep 2020'	Shannon Moyer (b) (4)	02 Sep 2020 14:02:40
	(b) (4)	

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '07:47'	Shannon Moyer (b) (4)	02 Sep 2020 14:02:40
	(b) (4)	

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '01 Sep 2020 07:47'	System	02 Sep 2020 14:02:40

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '65' in	Shannon Moyer (b) (4)	02 Sep 2020 14:02:40
DataPoint set to visible.	(b) (4) System	01 Sep 2020 13:43:13

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '179' lb	Shannon Moyer (b) (4)	02 Sep 2020 14:02:40
DataPoint set to visible.	(b) (4) System	01 Sep 2020 13:43:13

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '29.84944'	System	02 Sep 2020 14:02:40
DataPoint set to visible.	System	01 Sep 2020 13:43:13

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'kg/m2'	System	02 Sep 2020 14:02:40
DataPoint set to visible.	System	01 Sep 2020 13:43:13

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	02 Sep 2020 14:02:40
	(b) (4)	

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:02:40
	(b) (4)	

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:02:40
	(b) (4)	

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	02 Sep 2020 14:02:40
	(b) (4)	

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'bpm'	System	02 Sep 2020 14:02:40

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	02 Sep 2020 14:02:40
	(b) (4)	

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'breaths/min'	System	02 Sep 2020 14:02:40

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	02 Sep 2020 14:02:40
	(b) (4)	

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'mmHg'	System	02 Sep 2020 14:02:40

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	02 Sep 2020 14:02:40
	(b) (4)	

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'mmHg'	System	02 Sep 2020 14:02:40

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05

US3252399

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05

US3252399

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	02 Sep 2020 14:02:52
	(b) (4)	

US3252399

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:00

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '01 Sep 2020'	Shannon Moyer (b) (4)	02 Sep 2020 14:02:52
	(b) (4)	

US3252399

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:14:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '01 Sep 2020'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:23
	(b) (4)	

US3252399

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:14:00

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:23
	(b) (4)	

US3252399

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:14:00

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 15:22:36
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' answered with 'UPDATED' (Site from DM).	Xavier Morales (b) (4)	21 Oct 2020 17:28:21
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 09:05:52
User entered 'Surgically sterile (SURGICALLY STERILE)'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:23

US3252399

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:14:00

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:03:23
	(b) (4)	

US3252399

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'UN Jan 2013'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:23
	(b) (4)	

US3252399

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:14:00

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:23
	(b) (4)	

US3252399

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:03:23
	(b) (4)	

US3252399

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:14:00

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:23
	(b) (4)	

US3252399

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

US3252399

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

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)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

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)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

US3252399

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

US3252399

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

[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)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

US3252399

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

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)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

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)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

US3252399

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

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)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

US3252399

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

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)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

US3252399

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

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)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

US3252399

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

US3252399

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

US3252399

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

US3252399

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

US3252399

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

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)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

US3252399

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

[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)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

US3252399

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

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)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

US3252399

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'I'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

US3252399

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

US3252399

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:00

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:03:52
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	02 Sep 2020 14:04:07
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '01 Sep 2020'	Shannon Moyer (b) (4)	02 Sep 2020 14:04:07
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[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 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4)	02 Sep 2020 14:04:07
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'VISIT1'	System	02 Sep 2020 14:04:07

US3252399

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '01 SEP 2020'	RWS_ENDPOINT	01 Sep 2020 13:15:26
	ENDPOINT (b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:00

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '110156'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:15:26

US3252399

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:15:26

US3252399

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:00

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 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:04:28
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:00

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 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:04:28
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:04:28
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:00

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:04:28
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:00

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:04:28
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Nancy Torrence (b) (4)	29 Sep 2020 03:12:01
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:52:27
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:52:26

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:00

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 14:05:47

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '01 Sep 2020'	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '07:47'	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered '01 Sep 2020 07:47'	System	02 Sep 2020 14:05:47

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '98.3' F	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '83'	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'bpm'	System	02 Sep 2020 14:05:47

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '16'	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'breaths/min'	System	02 Sep 2020 14:05:47

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '115'	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'mmHg'	System	02 Sep 2020 14:05:47

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '80'	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'mmHg'	System	02 Sep 2020 14:05:47

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 14:05:47

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '01 Sep 2020'	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '09:15'	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered '01 Sep 2020 09:15'	System	02 Sep 2020 14:05:47

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '97.7' F	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '80'	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'bpm'	System	02 Sep 2020 14:05:47

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '15'	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'breaths/min'	System	02 Sep 2020 14:05:47

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '106'	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'mmHg'	System	02 Sep 2020 14:05:47

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '77'	Shannon Moyer (b) (4)	02 Sep 2020 14:05:47
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'mmHg'	System	02 Sep 2020 14:05:47

US3252399

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:05:54
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:00

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:05:54
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	01 Sep 2020 13:46:41

US3252399

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Joanna Gurrola Mahoney (b) (4)	01 Sep 2020 13:46:41

US3252399

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

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 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Joanna Gurrola Mahoney (b) (4)	01 Sep 2020 13:46:41

US3252399

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 13:46:41

US3252399

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '1 Sep 2020'	Joanna Gurrola Mahoney (b) (4)	01 Sep 2020 13:46:41

US3252399

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '08:39'	Joanna Gurrola Mahoney (b) (4)	01 Sep 2020 13:46:41

US3252399

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered '1 Sep 2020 08:39'	System	01 Sep 2020 13:46:41

US3252399

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola Mahoney	01 Sep 2020 13:46:41
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'ONCE'	System	01 Sep 2020 13:46:41

US3252399

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 13:46:41

US3252399

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	02 Sep 2020 14:06:17
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '01 Sep 2020'	Shannon Moyer (b) (4)	02 Sep 2020 14:06:17
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '08:27'	Shannon Moyer (b) (4)	02 Sep 2020 14:06:17
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered '01 Sep 2020 08:27'	System	02 Sep 2020 14:06:17

US3252399

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:14:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '01 Sep 2020'	Shannon Moyer (b) (4)	02 Sep 2020 14:06:39
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:00

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 14:06:39

US3252399

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	02 Sep 2020 14:06:39
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '08:18'	Shannon Moyer (b) (4)	02 Sep 2020 14:06:39
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered '01 Sep 2020 08:18'	System	02 Sep 2020 14:06:39

US3252399

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:00

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4)	02 Sep 2020 14:06:39
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:06:39
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:06:39
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered empty.	System	02 Sep 2020 14:06:39

US3252399

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	02 Sep 2020 14:06:45
	(b) (4)	

US3252399

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'I'	System	02 Sep 2020 14:06:45

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-01T09:19:12', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'f892eef1-7f28-45d2-a48f-47652dc4ad93' User entered 'Yes (Y)'	System	01 Sep 2020 14:19:27
	System	01 Sep 2020 14:19:27

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-01T09:19:17', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'f892eef1-7f28-45d2-a48f-47652dc4ad93' User entered '97.7'	System	01 Sep 2020 14:19:27
	System	01 Sep 2020 14:19:27

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-01T09:19:20', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'f892eef1-7f28-45d2-a48f-47652dc4ad93' User entered 'No (N)'	System	01 Sep 2020 14:19:27
	System	01 Sep 2020 14:19:27

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-01T09:19:21', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'f892eef1-7f28-45d2-a48f-47652dc4ad93'	System	01 Sep 2020 14:19:27
User entered '01 Sep 2020 09:19'	System	01 Sep 2020 14:19:27

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '01 Sep 2020 08:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '01 Sep 2020 11:29'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-02T10:48:35', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '49997cc7-a713-452f-9707-fb5d547f988f' User entered 'Yes (Y)'	System	02 Sep 2020 15:49:00
	System	02 Sep 2020 15:49:00

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-02T10:48:41', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '49997cc7-a713-452f-9707-fb5d547f988f' User entered '96.8'	System	02 Sep 2020 15:49:00
	System	02 Sep 2020 15:49:00

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-02T10:48:49', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '49997cc7-a713-452f-9707-fb5d547f988f' User entered 'No (N)'	System	02 Sep 2020 15:49:00
	System	02 Sep 2020 15:49:00

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-02T10:48:58', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '49997cc7-a713-452f-9707-fb5d547f988f' User entered '02 Sep 2020 10:48'	System	02 Sep 2020 15:49:00
	System	02 Sep 2020 15:49:00

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '01 Sep 2020 12:24'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 2'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-03T11:56:35', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'ce299b82-de80-423c-af0f-3b7a778c15fb' User entered 'Yes (Y)'	System	03 Sep 2020 16:57:00
	System	03 Sep 2020 16:57:00

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-03T11:56:40', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'ce299b82-de80-423c-af0f-3b7a778c15fb' User entered '98.2'	System	03 Sep 2020 16:57:00
	System	03 Sep 2020 16:57:00

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-03T11:56:45', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'ce299b82-de80-423c-af0f-3b7a778c15fb' User entered 'No (N)'	System	03 Sep 2020 16:57:00
	System	03 Sep 2020 16:57:00

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-03T11:56:57', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'ce299b82-de80-423c-af0f-3b7a778c15fb' User entered '03 Sep 2020 11:56'	System	03 Sep 2020 16:57:00
	System	03 Sep 2020 16:57:00

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 3'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-04T11:07:29', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'e1646f87-8e8a-40d0-98cf-b388f6d97c5c' User entered 'Yes (Y)'	System	04 Sep 2020 16:08:07
	System	04 Sep 2020 16:08:07

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-04T11:07:35', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'e1646f87-8e8a-40d0-98cf-b388f6d97c5c' User entered '98.3'	System	04 Sep 2020 16:08:07
	System	04 Sep 2020 16:08:07

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-04T11:07:38', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'e1646f87-8e8a-40d0-98cf-b388f6d97c5c'	System	04 Sep 2020 16:08:07
User entered 'No (N)'	System	04 Sep 2020 16:08:07

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-04T11:07:59', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'e1646f87-8e8a-40d0-98cf-b388f6d97c5c'	System	04 Sep 2020 16:08:07
User entered '04 Sep 2020 11:07'	System	04 Sep 2020 16:08:07

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 4'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-05T09:52:43', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '9bad75dd-8052-426e-91a9-d5660131f5ad' User entered 'Yes (Y)'	System	05 Sep 2020 14:53:05
	System	05 Sep 2020 14:53:05

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-05T09:52:48', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '9bad75dd-8052-426e-91a9-d5660131f5ad' User entered '97.7'	System	05 Sep 2020 14:53:05
	System	05 Sep 2020 14:53:05

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-05T09:52:50', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '9bad75dd-8052-426e-91a9-d5660131f5ad' User entered 'No (N)'	System	05 Sep 2020 14:53:05
	System	05 Sep 2020 14:53:05

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-05T09:53:01', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '9bad75dd-8052-426e-91a9-d5660131f5ad' User entered '05 Sep 2020 09:53'	System	05 Sep 2020 14:53:05
	System	05 Sep 2020 14:53:05

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 5'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-06T11:38:45', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'ecfbe58a-618a-4a38-9b97-00d241859d8c' User entered 'Yes (Y)'	System	06 Sep 2020 16:39:52
	System	06 Sep 2020 16:39:52

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-06T11:39:03', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'ecfbe58a-618a-4a38-9b97-00d241859d8c' User entered '94.9'	System	06 Sep 2020 16:39:52
	System	06 Sep 2020 16:39:52

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-06T11:39:07', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'ecfbe58a-618a-4a38-9b97-00d241859d8c' User entered 'No (N)'	System	06 Sep 2020 16:39:52
	System	06 Sep 2020 16:39:52

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-06T11:39:50', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'ecfbe58a-618a-4a38-9b97-00d241859d8c' User entered '06 Sep 2020 11:39'	System	06 Sep 2020 16:39:52
	System	06 Sep 2020 16:39:52

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 6'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:00

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 7'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-08T11:37:08', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '0ff43c56-2c39-486b-a12d-f3a940166002'	System	08 Sep 2020 16:37:26
User entered 'Yes (Y)'	System	08 Sep 2020 16:37:26

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-08T11:37:14', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '0ff43c56-2c39-486b-a12d-f3a940166002' User entered '98.1'	System	08 Sep 2020 16:37:26
	System	08 Sep 2020 16:37:26

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-08T11:37:17', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '0ff43c56-2c39-486b-a12d-f3a940166002'	System	08 Sep 2020 16:37:26
User entered 'No (N)'	System	08 Sep 2020 16:37:26

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-08T11:37:24', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '0ff43c56-2c39-486b-a12d-f3a940166002'	System	08 Sep 2020 16:37:26
User entered '08 Sep 2020 11:37'	System	08 Sep 2020 16:37:26

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-01T09:19:25', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'b75136bd-ebf2-46e2-99a1-bc48aba06b30' User entered 'None (1)'	System	01 Sep 2020 14:19:38
	System	01 Sep 2020 14:19:38

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-01T09:19:27', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'b75136bd-ebf2-46e2-99a1-bc48aba06b30' User entered 'No (N)'	System	01 Sep 2020 14:19:38
	System	01 Sep 2020 14:19:38

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-01T09:19:29', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'b75136bd-ebf2-46e2-99a1-bc48aba06b30' User entered 'No (N)'	System	01 Sep 2020 14:19:38
	System	01 Sep 2020 14:19:38

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-01T09:19:33', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'b75136bd-ebf2-46e2-99a1-bc48aba06b30' User entered 'None (1)'	System	01 Sep 2020 14:19:38
	System	01 Sep 2020 14:19:38

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-01T09:19:36', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'b75136bd-ebf2-46e2-99a1-bc48aba06b30' User entered '01 Sep 2020 09:19'	System	01 Sep 2020 14:19:38
	System	01 Sep 2020 14:19:38

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '01 Sep 2020 08:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '01 Sep 2020 11:29'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-02T10:49:09', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '6c7aa3e7-0df5-431d-8648-b1e554a6b4ad'	System	02 Sep 2020 15:50:01
User entered 'None (1)'	System	02 Sep 2020 15:50:01

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-02T10:49:34', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '6c7aa3e7-0df5-431d-8648-b1e554a6b4ad' User entered 'No (N)'	System	02 Sep 2020 15:50:01
	System	02 Sep 2020 15:50:01

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-02T10:49:38', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '6c7aa3e7-0df5-431d-8648-b1e554a6b4ad' User entered 'No (N)'	System	02 Sep 2020 15:50:01
	System	02 Sep 2020 15:50:01

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-02T10:49:47', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '6c7aa3e7-0df5-431d-8648-b1e554a6b4ad'	System	02 Sep 2020 15:50:01
User entered 'None (1)'	System	02 Sep 2020 15:50:01

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-02T10:49:57', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '6c7aa3e7-0df5-431d-8648-b1e554a6b4ad' User entered '02 Sep 2020 10:49'	System	02 Sep 2020 15:50:01
	System	02 Sep 2020 15:50:01

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '01 Sep 2020 12:24'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 2'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-03T11:57:04', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'b275c1cc-c8fa-4e50-b3d8-c89628daf5ef' User entered 'None (1)'	System	03 Sep 2020 16:57:23
	System	03 Sep 2020 16:57:23

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-03T11:57:07', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'b275c1cc-c8fa-4e50-b3d8-c89628daf5ef' User entered 'No (N)'	System	03 Sep 2020 16:57:23
	System	03 Sep 2020 16:57:23

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-03T11:57:10', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'b275c1cc-c8fa-4e50-b3d8-c89628daf5ef' User entered 'No (N)'	System	03 Sep 2020 16:57:23
	System	03 Sep 2020 16:57:23

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-03T11:57:14', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'b275c1cc-c8fa-4e50-b3d8-c89628daf5ef' User entered 'None (1)'	System	03 Sep 2020 16:57:23
	System	03 Sep 2020 16:57:23

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-03T11:57:19', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'b275c1cc-c8fa-4e50-b3d8-c89628daf5ef' User entered '03 Sep 2020 11:57'	System	03 Sep 2020 16:57:23
	System	03 Sep 2020 16:57:23

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 3'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-04T11:08:07', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'e46c88a3-d9c5-45a4-90b9-0bd2a758efb3' User entered 'None (1)'	System	04 Sep 2020 16:08:30
	System	04 Sep 2020 16:08:30

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-04T11:08:09', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'e46c88a3-d9c5-45a4-90b9-0bd2a758efb3' User entered 'No (N)'	System	04 Sep 2020 16:08:30
	System	04 Sep 2020 16:08:30

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-04T11:08:12', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'e46c88a3-d9c5-45a4-90b9-0bd2a758efb3' User entered 'No (N)'	System	04 Sep 2020 16:08:30
	System	04 Sep 2020 16:08:30

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-04T11:08:14', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'e46c88a3-d9c5-45a4-90b9-0bd2a758efb3'	System	04 Sep 2020 16:08:30
User entered 'None (1)'	System	04 Sep 2020 16:08:30

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-04T11:08:23', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'e46c88a3-d9c5-45a4-90b9-0bd2a758efb3' User entered '04 Sep 2020 11:08'	System	04 Sep 2020 16:08:30
	System	04 Sep 2020 16:08:30

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 4'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-05T09:53:05', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'c3d046ce-8095-4c64-936f-d109e75e88a4'	System	05 Sep 2020 14:53:21
User entered 'None (1)'	System	05 Sep 2020 14:53:21

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-05T09:53:08', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'c3d046ce-8095-4c64-936f-d109e75e88a4' User entered 'No (N)'	System	05 Sep 2020 14:53:21
	System	05 Sep 2020 14:53:21

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-05T09:53:10', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'c3d046ce-8095-4c64-936f-d109e75e88a4' User entered 'No (N)'	System	05 Sep 2020 14:53:21
	System	05 Sep 2020 14:53:21

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-05T09:53:13', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'c3d046ce-8095-4c64-936f-d109e75e88a4'	System	05 Sep 2020 14:53:21
User entered 'None (1)'	System	05 Sep 2020 14:53:21

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-05T09:53:19', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'c3d046ce-8095-4c64-936f-d109e75e88a4' User entered '05 Sep 2020 09:53'	System	05 Sep 2020 14:53:21
	System	05 Sep 2020 14:53:21

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 5'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-06T11:39:54', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '5e421c4d-de3e-4e98-b41c-44f4a58b9b1a' User entered 'None (1)'	System	06 Sep 2020 16:40:11
	System	06 Sep 2020 16:40:11

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-06T11:39:57', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '5e421c4d-de3e-4e98-b41c-44f4a58b9b1a' User entered 'No (N)'	System	06 Sep 2020 16:40:11
	System	06 Sep 2020 16:40:11

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-06T11:39:59', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '5e421c4d-de3e-4e98-b41c-44f4a58b9b1a' User entered 'No (N)'	System	06 Sep 2020 16:40:11
	System	06 Sep 2020 16:40:11

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-06T11:40:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '5e421c4d-de3e-4e98-b41c-44f4a58b9b1a' User entered 'None (1)'	System	06 Sep 2020 16:40:11
	System	06 Sep 2020 16:40:11

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-06T11:40:09', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '5e421c4d-de3e-4e98-b41c-44f4a58b9b1a' User entered '06 Sep 2020 11:40'	System	06 Sep 2020 16:40:11
	System	06 Sep 2020 16:40:11

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 6'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 7'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-08T11:37:28', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '8afe798e-8961-495c-ac9f-58be35a665c9' User entered 'None (1)'	System	08 Sep 2020 16:37:47
	System	08 Sep 2020 16:37:47

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-08T11:37:30', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '8afe798e-8961-495c-ac9f-58be35a665c9' User entered 'No (N)'	System	08 Sep 2020 16:37:47
	System	08 Sep 2020 16:37:47

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-08T11:37:32', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '8afe798e-8961-495c-ac9f-58be35a665c9' User entered 'No (N)'	System	08 Sep 2020 16:37:47
	System	08 Sep 2020 16:37:47

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-08T11:37:34', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '8afe798e-8961-495c-ac9f-58be35a665c9' User entered 'None (1)'	System	08 Sep 2020 16:37:47
	System	08 Sep 2020 16:37:47

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-08T11:37:43', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '8afe798e-8961-495c-ac9f-58be35a665c9' User entered '08 Sep 2020 11:37'	System	08 Sep 2020 16:37:47
	System	08 Sep 2020 16:37:47

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-01T09:19:38', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '43cda15b-91c9-406a-92df-a60a1dea0518' User entered 'None (0)'	System	01 Sep 2020 14:20:01
	System	01 Sep 2020 14:20:01

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-01T09:19:40', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '43cda15b-91c9-406a-92df-a60a1dea0518' User entered 'None (0)'	System	01 Sep 2020 14:20:01
	System	01 Sep 2020 14:20:01

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-01T09:19:41', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '43cda15b-91c9-406a-92df-a60a1dea0518' User entered 'None (0)'	System	01 Sep 2020 14:20:01
	System	01 Sep 2020 14:20:01

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-01T09:19:42', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '43cda15b-91c9-406a-92df-a60a1dea0518' User entered 'None (0)'	System	01 Sep 2020 14:20:01
	System	01 Sep 2020 14:20:01

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-01T09:19:43', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '43cda15b-91c9-406a-92df-a60a1dea0518' User entered 'None (0)'	System	01 Sep 2020 14:20:01
	System	01 Sep 2020 14:20:01

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-01T09:19:44', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '43cda15b-91c9-406a-92df-a60a1dea0518' User entered 'None (0)'	System	01 Sep 2020 14:20:01
	System	01 Sep 2020 14:20:01

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-01T09:19:57', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '43cda15b-91c9-406a-92df-a60a1dea0518' User entered 'No (N)'	System	01 Sep 2020 14:20:01
	System	01 Sep 2020 14:20:01

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-01T09:20:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '43cda15b-91c9-406a-92df-a60a1dea0518' User entered '01 Sep 2020 09:20'	System	01 Sep 2020 14:20:01
	System	01 Sep 2020 14:20:01

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '01 Sep 2020 08:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '01 Sep 2020 11:29'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-02T10:50:03', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'da9985bb-504a-47d9-b629-937df0669d5c' User entered 'None (0)'	System	02 Sep 2020 15:50:33
	System	02 Sep 2020 15:50:33

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-02T10:50:06', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'da9985bb-504a-47d9-b629-937df0669d5c' User entered 'None (0)'	System	02 Sep 2020 15:50:33
	System	02 Sep 2020 15:50:33

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-02T10:50:08', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'da9985bb-504a-47d9-b629-937df0669d5c' User entered 'None (0)'	System	02 Sep 2020 15:50:33
	System	02 Sep 2020 15:50:33

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-02T10:50:15', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'da9985bb-504a-47d9-b629-937df0669d5c' User entered 'None (0)'	System	02 Sep 2020 15:50:33
	System	02 Sep 2020 15:50:33

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-02T10:50:17', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'da9985bb-504a-47d9-b629-937df0669d5c' User entered 'None (0)'	System	02 Sep 2020 15:50:33
	System	02 Sep 2020 15:50:33

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-02T10:50:19', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'da9985bb-504a-47d9-b629-937df0669d5c' User entered 'None (0)'	System	02 Sep 2020 15:50:33
	System	02 Sep 2020 15:50:33

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-02T10:50:24', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'da9985bb-504a-47d9-b629-937df0669d5c' User entered 'No (N)'	System	02 Sep 2020 15:50:33
	System	02 Sep 2020 15:50:33

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-02T10:50:30', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'da9985bb-504a-47d9-b629-937df0669d5c' User entered '02 Sep 2020 10:50'	System	02 Sep 2020 15:50:33
	System	02 Sep 2020 15:50:33

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '01 Sep 2020 12:24'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 2'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-03T11:57:24', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '99a52243-2834-410b-bca5-74437ca30f00' User entered 'None (0)'	System	03 Sep 2020 16:57:43
	System	03 Sep 2020 16:57:43

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-03T11:57:26', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '99a52243-2834-410b-bca5-74437ca30f00' User entered 'None (0)'	System	03 Sep 2020 16:57:43
	System	03 Sep 2020 16:57:43

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-03T11:57:28', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '99a52243-2834-410b-bca5-74437ca30f00' User entered 'None (0)'	System	03 Sep 2020 16:57:43
	System	03 Sep 2020 16:57:43

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-03T11:57:31', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '99a52243-2834-410b-bca5-74437ca30f00' User entered 'None (0)'	System	03 Sep 2020 16:57:43
	System	03 Sep 2020 16:57:43

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-03T11:57:33', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '99a52243-2834-410b-bca5-74437ca30f00' User entered 'None (0)'	System	03 Sep 2020 16:57:43
	System	03 Sep 2020 16:57:43

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-03T11:57:35', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '99a52243-2834-410b-bca5-74437ca30f00' User entered 'None (0)'	System	03 Sep 2020 16:57:43
	System	03 Sep 2020 16:57:43

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-03T11:57:38', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '99a52243-2834-410b-bca5-74437ca30f00' User entered 'No (N)'	System	03 Sep 2020 16:57:43
	System	03 Sep 2020 16:57:43

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-03T11:57:42', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '99a52243-2834-410b-bca5-74437ca30f00' User entered '03 Sep 2020 11:57'	System	03 Sep 2020 16:57:43
	System	03 Sep 2020 16:57:43

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 3'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-04T11:08:31', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '1d481e49-6744-402e-be6d-4a1e1c2ce310' User entered 'None (0)'	System	04 Sep 2020 16:08:56
	System	04 Sep 2020 16:08:56

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-04T11:08:33', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '1d481e49-6744-402e-be6d-4a1e1c2ce310' User entered 'None (0)'	System	04 Sep 2020 16:08:56
	System	04 Sep 2020 16:08:56

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-04T11:08:35', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '1d481e49-6744-402e-be6d-4a1e1c2ce310' User entered 'None (0)'	System	04 Sep 2020 16:08:56
	System	04 Sep 2020 16:08:56

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-04T11:08:37', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '1d481e49-6744-402e-be6d-4a1e1c2ce310' User entered 'None (0)'	System	04 Sep 2020 16:08:56
	System	04 Sep 2020 16:08:56

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-04T11:08:39', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '1d481e49-6744-402e-be6d-4a1e1c2ce310' User entered 'None (0)'	System	04 Sep 2020 16:08:56
	System	04 Sep 2020 16:08:56

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-04T11:08:41', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '1d481e49-6744-402e-be6d-4a1e1c2ce310' User entered 'None (0)'	System	04 Sep 2020 16:08:56
	System	04 Sep 2020 16:08:56

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-04T11:08:50', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '1d481e49-6744-402e-be6d-4a1e1c2ce310' User entered 'No (N)'	System	04 Sep 2020 16:08:56
	System	04 Sep 2020 16:08:56

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-04T11:08:53', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '1d481e49-6744-402e-be6d-4a1e1c2ce310' User entered '04 Sep 2020 11:08'	System	04 Sep 2020 16:08:56
	System	04 Sep 2020 16:08:56

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 4'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-05T09:53:23', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '2696d5e3-e9dd-498e-8df0-03d1152854c4' User entered 'None (0)'	System	05 Sep 2020 14:53:40
	System	05 Sep 2020 14:53:40

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-05T09:53:25', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '2696d5e3-e9dd-498e-8df0-03d1152854c4' User entered 'None (0)'	System	05 Sep 2020 14:53:40
	System	05 Sep 2020 14:53:40

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-05T09:53:27', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '2696d5e3-e9dd-498e-8df0-03d1152854c4' User entered 'None (0)'	System	05 Sep 2020 14:53:40
	System	05 Sep 2020 14:53:40

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-05T09:53:29', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '2696d5e3-e9dd-498e-8df0-03d1152854c4' User entered 'None (0)'	System	05 Sep 2020 14:53:40
	System	05 Sep 2020 14:53:40

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-05T09:53:32', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '2696d5e3-e9dd-498e-8df0-03d1152854c4' User entered 'None (0)'	System	05 Sep 2020 14:53:40
	System	05 Sep 2020 14:53:40

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-05T09:53:34', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '2696d5e3-e9dd-498e-8df0-03d1152854c4' User entered 'None (0)'	System	05 Sep 2020 14:53:40
	System	05 Sep 2020 14:53:40

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-05T09:53:36', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '2696d5e3-e9dd-498e-8df0-03d1152854c4' User entered 'No (N)'	System	05 Sep 2020 14:53:40
	System	05 Sep 2020 14:53:40

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-05T09:53:38', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '2696d5e3-e9dd-498e-8df0-03d1152854c4' User entered '05 Sep 2020 09:53'	System	05 Sep 2020 14:53:40
	System	05 Sep 2020 14:53:40

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 5'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-06T11:40:13', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '298deecd-8157-4509-a43b-7b05d53e8b09' User entered 'None (0)'	System	06 Sep 2020 16:40:34
	System	06 Sep 2020 16:40:34

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-06T11:40:14', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '298deecd-8157-4509-a43b-7b05d53e8b09' User entered 'None (0)'	System	06 Sep 2020 16:40:34
	System	06 Sep 2020 16:40:34

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-06T11:40:16', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '298deecd-8157-4509-a43b-7b05d53e8b09' User entered 'None (0)'	System	06 Sep 2020 16:40:34
	System	06 Sep 2020 16:40:34

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-06T11:40:18', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '298deecd-8157-4509-a43b-7b05d53e8b09' User entered 'None (0)'	System	06 Sep 2020 16:40:34
	System	06 Sep 2020 16:40:34

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-06T11:40:20', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '298deecd-8157-4509-a43b-7b05d53e8b09' User entered 'None (0)'	System	06 Sep 2020 16:40:34
	System	06 Sep 2020 16:40:34

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-06T11:40:21', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '298deecd-8157-4509-a43b-7b05d53e8b09' User entered 'None (0)'	System	06 Sep 2020 16:40:34
	System	06 Sep 2020 16:40:34

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-06T11:40:24', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '298deecd-8157-4509-a43b-7b05d53e8b09' User entered 'No (N)'	System	06 Sep 2020 16:40:34
	System	06 Sep 2020 16:40:34

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-06T11:40:32', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '298deecd-8157-4509-a43b-7b05d53e8b09' User entered '06 Sep 2020 11:40'	System	06 Sep 2020 16:40:34
	System	06 Sep 2020 16:40:34

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 6'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 7'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-08T11:37:47', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '6f30d2a0-0749-4bcc-bafa-c130f7eebecb' User entered 'None (0)'	System	08 Sep 2020 16:38:05
	System	08 Sep 2020 16:38:05

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-08T11:37:48', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '6f30d2a0-0749-4bcc-bafa-c130f7eebecb' User entered 'None (0)'	System	08 Sep 2020 16:38:05
	System	08 Sep 2020 16:38:05

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-08T11:37:50', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '6f30d2a0-0749-4bcc-bafa-c130f7eebecb' User entered 'None (0)'	System	08 Sep 2020 16:38:05
	System	08 Sep 2020 16:38:05

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-08T11:37:52', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '6f30d2a0-0749-4bcc-bafa-c130f7eebecb' User entered 'None (0)'	System	08 Sep 2020 16:38:05
	System	08 Sep 2020 16:38:05

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-08T11:37:54', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '6f30d2a0-0749-4bcc-bafa-c130f7eebecb' User entered 'None (0)'	System	08 Sep 2020 16:38:05
	System	08 Sep 2020 16:38:05

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-08T11:37:56', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '6f30d2a0-0749-4bcc-bafa-c130f7eebecb' User entered 'None (0)'	System	08 Sep 2020 16:38:05
	System	08 Sep 2020 16:38:05

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-08T11:38:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '6f30d2a0-0749-4bcc-bafa-c130f7eebecb' User entered 'No (N)'	System	08 Sep 2020 16:38:05
	System	08 Sep 2020 16:38:05

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-08T11:38:01', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '6f30d2a0-0749-4bcc-bafa-c130f7eebecb' User entered '08 Sep 2020 11:38'	System	08 Sep 2020 16:38:05
	System	08 Sep 2020 16:38:05

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 13:46:41

US3252399

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	09 Sep 2020 00:54:28
	(b) (4)	

US3252399

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '8 Sep 2020'	Shannon Moyer (b) (4)	09 Sep 2020 00:54:28
	(b) (4)	

US3252399

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	09 Sep 2020 00:54:28
	(b) (4)	

US3252399

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Shannon Moyer (b) (4)	09 Sep 2020 00:54:28
	(b) (4)	

US3252399

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	09 Sep 2020 00:54:40
	(b) (4)	

US3252399

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'I'	System	09 Sep 2020 00:54:40

US3252399

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:04
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	16 Sep 2020 03:39:17
	(b) (4)	

US3252399

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:04
User entered '15 Sep 2020'	Nancy Torrence (b) (4)	16 Sep 2020 03:39:17
	(b) (4)	

US3252399

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:04
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	16 Sep 2020 03:39:17
	(b) (4)	

US3252399

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:04
User entered empty.	Nancy Torrence (b) (4)	16 Sep 2020 03:39:17
	(b) (4)	

US3252399

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:04
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	16 Sep 2020 03:39:23
	(b) (4)	

US3252399

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'I'	System	16 Sep 2020 03:39:23

US3252399

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:04
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	23 Sep 2020 01:24:32
	(b) (4)	

US3252399

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:04
User entered '22 Sep 2020'	Nancy Torrence (b) (4)	23 Sep 2020 01:24:32
	(b) (4)	

US3252399

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:04
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	23 Sep 2020 01:24:32
	(b) (4)	

US3252399

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:04
User entered empty.	Nancy Torrence (b) (4)	23 Sep 2020 01:24:32
	(b) (4)	

US3252399

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:04
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	23 Sep 2020 01:24:41
	(b) (4)	

US3252399

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'I'	System	23 Sep 2020 01:24:41

US3252399

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	29 Sep 2020 03:07:19
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '28 Sep 2020'	Nancy Torrence (b) (4)	29 Sep 2020 03:07:19
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[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 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Clinic (Clinic)'	Nancy Torrence (b) (4)	29 Sep 2020 03:07:19
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'VISIT2'	System	29 Sep 2020 03:07:19

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User accepted default value 'Pre-Dose (PREDOSE)'	Nancy Torrence (b) (4) (b) (4)	29 Sep 2020 03:09:26

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '28 Sep 2020'	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '07:20'	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered '28 Sep 2020 07:20'	System	29 Sep 2020 03:09:26

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '97.4' F	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Oral (Oral)'	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '82'	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'bpm'	System	29 Sep 2020 03:09:26

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '15'	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'breaths/min'	System	29 Sep 2020 03:09:26

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '110'	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'mmHg'	System	29 Sep 2020 03:09:26

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '81'	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'mmHg'	System	29 Sep 2020 03:09:26

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User accepted default value 'Post-Dose (POSTDOSE)'	Nancy Torrence (b) (4) (b) (4)	29 Sep 2020 03:09:26

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '28 Sep 2020'	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '08:56'	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered '28 Sep 2020 08:56'	System	29 Sep 2020 03:09:26

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '96.9' F	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Oral (Oral)'	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '74'	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'bpm'	System	29 Sep 2020 03:09:26

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '18'	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'breaths/min'	System	29 Sep 2020 03:09:26

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '124'	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'mmHg'	System	29 Sep 2020 03:09:26

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '86'	Nancy Torrence (b) (4)	29 Sep 2020 03:09:26
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'mmHg'	System	29 Sep 2020 03:09:26

US3252399

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Nancy Torrence (b) (4)	29 Sep 2020 03:09:53
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Nancy Torrence (b) (4)	29 Sep 2020 03:09:53
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Joanna Gurrola Mahoney	28 Sep 2020 14:00:19
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Joanna Gurrola Mahoney (b) (4)	28 Sep 2020 14:00:19

US3252399

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

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 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Joanna Gurrola Mahoney (b) (4)	28 Sep 2020 14:00:19

US3252399

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 14:00:19

US3252399

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '28 Sep 2020'	Joanna Gurrola Mahoney (b) (4)	28 Sep 2020 14:00:19

US3252399

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '08:26'	Joanna Gurrola Mahoney (b) (4)	28 Sep 2020 14:00:19

US3252399

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered '28 Sep 2020 08:26'	System	28 Sep 2020 14:00:19

US3252399

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola Mahoney	28 Sep 2020 14:00:19
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'ONCE'	System	28 Sep 2020 14:00:19

US3252399

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 14:00:19

US3252399

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	29 Sep 2020 03:10:18
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '28 Sep 2020'	Nancy Torrence (b) (4)	29 Sep 2020 03:10:18
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '07:42'	Nancy Torrence (b) (4)	29 Sep 2020 03:10:18
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered '28 Sep 2020 07:42'	System	29 Sep 2020 03:10:18

US3252399

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:14:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '28 Sep 2020'	Nancy Torrence (b) (4)	29 Sep 2020 03:10:43
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:00

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nancy Torrence (b) (4) (b) (4)	29 Sep 2020 03:10:43

US3252399

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	29 Sep 2020 03:10:43
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '07:30'	Nancy Torrence (b) (4)	29 Sep 2020 03:10:43
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered '28 Sep 2020 07:30'	System	29 Sep 2020 03:10:43

US3252399

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:00

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nancy Torrence (b) (4) (b) (4)	29 Sep 2020 03:10:43

US3252399

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Nancy Torrence (b) (4)	29 Sep 2020 03:10:43
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Nancy Torrence (b) (4)	29 Sep 2020 03:10:43
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered empty.	System	29 Sep 2020 03:10:43

US3252399

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	29 Sep 2020 03:10:49
	(b) (4)	

US3252399

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered '1'	System	29 Sep 2020 03:10:49

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T09:00:45', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '78f3451b-2ed0-4d60-bff6-b03095ba9845' User entered 'Yes (Y)'	System	28 Sep 2020 14:01:00
	System	28 Sep 2020 14:01:00

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T09:00:49', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '78f3451b-2ed0-4d60-bff6-b03095ba9845' User entered '97.2'	System	28 Sep 2020 14:01:00
	System	28 Sep 2020 14:01:00

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T09:00:52', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '78f3451b-2ed0-4d60-bff6-b03095ba9845' User entered 'No (N)'	System	28 Sep 2020 14:01:00
	System	28 Sep 2020 14:01:00

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T09:00:58', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '78f3451b-2ed0-4d60-bff6-b03095ba9845' User entered '28 Sep 2020 09:00'	System	28 Sep 2020 14:01:00
	System	28 Sep 2020 14:01:00

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '28 Sep 2020 08:46'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '28 Sep 2020 11:16'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T19:33:23', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '0486ebf0-cd88-4d61-9c83-de9aecebec6'	System	29 Sep 2020 00:33:39
User entered 'Yes (Y)'	System	29 Sep 2020 00:33:39

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T19:33:27', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '0486ebf0-cd88-4d61-9c83-de9aecebec6' User entered '97.7'	System	29 Sep 2020 00:33:39
	System	29 Sep 2020 00:33:39

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T19:33:30', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '0486ebf0-cd88-4d61-9c83-de9aecebec6' User entered 'No (N)'	System	29 Sep 2020 00:33:39
	System	29 Sep 2020 00:33:39

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T19:33:35', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '0486ebf0-cd88-4d61-9c83-de9aecebec6' User entered '28 Sep 2020 19:33'	System	29 Sep 2020 00:33:39
	System	29 Sep 2020 00:33:39

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '28 Sep 2020 12:11'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 2'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-29T23:46:22', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '61ff27da-bf2a-409d-8160-24b6b5867be4' User entered 'Yes (Y)'	System	30 Sep 2020 04:46:55
	System	30 Sep 2020 04:46:55

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-29T23:46:47', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '61ff27da-bf2a-409d-8160-24b6b5867be4' User entered '98.0'	System	30 Sep 2020 04:46:55
	System	30 Sep 2020 04:46:55

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-29T23:46:50', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '61ff27da-bf2a-409d-8160-24b6b5867be4' User entered 'No (N)'	System	30 Sep 2020 04:46:55
	System	30 Sep 2020 04:46:55

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-29T23:46:53', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '61ff27da-bf2a-409d-8160-24b6b5867be4' User entered '29 Sep 2020 23:46'	System	30 Sep 2020 04:46:55
	System	30 Sep 2020 04:46:55

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 3'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T06:49:29', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '3e6980aa-a950-402a-b970-5e05ce613b10' User entered 'Yes (Y)'	System	01 Oct 2020 11:49:44
	System	01 Oct 2020 11:49:44

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T06:49:34', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '3e6980aa-a950-402a-b970-5e05ce613b10' User entered '97.8'	System	01 Oct 2020 11:49:44
	System	01 Oct 2020 11:49:44

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T06:49:37', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '3e6980aa-a950-402a-b970-5e05ce613b10' User entered 'No (N)'	System	01 Oct 2020 11:49:44
	System	01 Oct 2020 11:49:44

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T06:49:42', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '3e6980aa-a950-402a-b970-5e05ce613b10' User entered '01 Oct 2020 06:49'	System	01 Oct 2020 11:49:44
	System	01 Oct 2020 11:49:44

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 4'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T21:07:21', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'f0202d96-0ddf-444c-95c3-01ba58dc2152'	System	02 Oct 2020 02:07:45
User entered 'Yes (Y)'	System	02 Oct 2020 02:07:45

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T21:07:25', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'f0202d96-0ddf-444c-95c3-01ba58dc2152' User entered '98.0'	System	02 Oct 2020 02:07:45
	System	02 Oct 2020 02:07:45

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T21:07:28', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'f0202d96-0ddf-444c-95c3-01ba58dc2152'	System	02 Oct 2020 02:07:45
User entered 'No (N)'	System	02 Oct 2020 02:07:45

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T21:07:41', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'f0202d96-0ddf-444c-95c3-01ba58dc2152'	System	02 Oct 2020 02:07:45
User entered '01 Oct 2020 21:07'	System	02 Oct 2020 02:07:45

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 5'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-02T19:39:21', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'e42b8fb6-c221-40ca-9616-cf40ae7bbbad' User entered 'Yes (Y)'	System	03 Oct 2020 00:39:44
	System	03 Oct 2020 00:39:44

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-02T19:39:33', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'e42b8fb6-c221-40ca-9616-cf40ae7bbbad' User entered '97.5'	System	03 Oct 2020 00:39:44
	System	03 Oct 2020 00:39:44

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-02T19:39:36', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'e42b8fb6-c221-40ca-9616-cf40ae7bbbad'	System	03 Oct 2020 00:39:44
User entered 'No (N)'	System	03 Oct 2020 00:39:44

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-02T19:39:39', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'e42b8fb6-c221-40ca-9616-cf40ae7bbbad' User entered '02 Oct 2020 19:39'	System	03 Oct 2020 00:39:44
	System	03 Oct 2020 00:39:44

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 6'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T10:28:37', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '341a60ba-63d2-42f5-b090-f39bf8b6f4b0' User entered 'Yes (Y)'	System	04 Oct 2020 15:29:09
	System	04 Oct 2020 15:29:09

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T10:28:57', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '341a60ba-63d2-42f5-b090-f39bf8b6f4b0' User entered '97.3'	System	04 Oct 2020 15:29:09
	System	04 Oct 2020 15:29:09

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T10:29:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '341a60ba-63d2-42f5-b090-f39bf8b6f4b0' User entered 'No (N)'	System	04 Oct 2020 15:29:09
	System	04 Oct 2020 15:29:09

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T10:29:05', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '341a60ba-63d2-42f5-b090-f39bf8b6f4b0' User entered '04 Oct 2020 10:29'	System	04 Oct 2020 15:29:09
	System	04 Oct 2020 15:29:09

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 7'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T22:09:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '5f09ccde-47c7-4734-b600-68abf0f2f174' User entered 'Yes (Y)'	System	05 Oct 2020 03:09:17
	System	05 Oct 2020 03:09:17

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T22:09:09', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '5f09ccde-47c7-4734-b600-68abf0f2f174' User entered '97.2'	System	05 Oct 2020 03:09:17
	System	05 Oct 2020 03:09:17

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T22:09:12', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '5f09ccde-47c7-4734-b600-68abf0f2f174'	System	05 Oct 2020 03:09:17
User entered 'No (N)'	System	05 Oct 2020 03:09:17

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T22:09:16', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '5f09ccde-47c7-4734-b600-68abf0f2f174' User entered '04 Oct 2020 22:09'	System	05 Oct 2020 03:09:17
	System	05 Oct 2020 03:09:17

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T09:01:05', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '4d5d7a91-006e-4614-929b-875da56481e7'	System	28 Sep 2020 14:01:19
User entered 'None (1)'	System	28 Sep 2020 14:01:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T09:01:09', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '4d5d7a91-006e-4614-929b-875da56481e7'	System	28 Sep 2020 14:01:19
User entered 'No (N)'	System	28 Sep 2020 14:01:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T09:01:11', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '4d5d7a91-006e-4614-929b-875da56481e7'	System	28 Sep 2020 14:01:19
User entered 'No (N)'	System	28 Sep 2020 14:01:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T09:01:13', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '4d5d7a91-006e-4614-929b-875da56481e7'	System	28 Sep 2020 14:01:19
User entered 'None (1)'	System	28 Sep 2020 14:01:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T09:01:15', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '4d5d7a91-006e-4614-929b-875da56481e7' User entered '28 Sep 2020 09:01'	System	28 Sep 2020 14:01:19
	System	28 Sep 2020 14:01:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '28 Sep 2020 08:46'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '28 Sep 2020 11:16'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T19:33:50', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '257aae49-9069-4020-99e4-7671bf45cdac' User entered 'None (1)'	System	29 Sep 2020 00:34:12
	System	29 Sep 2020 00:34:12

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T19:33:54', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '257aae49-9069-4020-99e4-7671bf45cdac' User entered 'No (N)'	System	29 Sep 2020 00:34:12
	System	29 Sep 2020 00:34:12

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T19:34:02', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '257aae49-9069-4020-99e4-7671bf45cdac' User entered 'No (N)'	System	29 Sep 2020 00:34:12
	System	29 Sep 2020 00:34:12

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T19:34:05', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '257aae49-9069-4020-99e4-7671bf45cdac'	System	29 Sep 2020 00:34:12
User entered 'None (1)'	System	29 Sep 2020 00:34:12

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T19:34:08', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '257aae49-9069-4020-99e4-7671bf45cdac' User entered '28 Sep 2020 19:34'	System	29 Sep 2020 00:34:12
	System	29 Sep 2020 00:34:12

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '28 Sep 2020 12:11'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 2'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-29T23:46:56', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '0b5f589d-523a-4791-8991-14bbdbcd6f23'	System	30 Sep 2020 04:47:10
User entered 'None (1)'	System	30 Sep 2020 04:47:10

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-29T23:46:59', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '0b5f589d-523a-4791-8991-14bbdbcd6f23'	System	30 Sep 2020 04:47:10
User entered 'No (N)'	System	30 Sep 2020 04:47:10

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-29T23:47:01', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '0b5f589d-523a-4791-8991-14bbdbcd6f23'	System	30 Sep 2020 04:47:10
User entered 'No (N)'	System	30 Sep 2020 04:47:10

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-29T23:47:04', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '0b5f589d-523a-4791-8991-14bbdbcd6f23'	System	30 Sep 2020 04:47:10
User entered 'None (1)'	System	30 Sep 2020 04:47:10

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-29T23:47:07', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '0b5f589d-523a-4791-8991-14bbdbcd6f23' User entered '29 Sep 2020 23:47'	System	30 Sep 2020 04:47:10
	System	30 Sep 2020 04:47:10

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 3'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T06:49:51', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '70b82ef1-b32c-4b79-8c09-48c9cb84393e'	System	01 Oct 2020 11:50:06
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 11:50:06

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T06:49:54', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '70b82ef1-b32c-4b79-8c09-48c9cb84393e' User entered 'No (N)'	System	01 Oct 2020 11:50:06
	System	01 Oct 2020 11:50:06

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T06:49:57', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '70b82ef1-b32c-4b79-8c09-48c9cb84393e' User entered 'No (N)'	System	01 Oct 2020 11:50:06
	System	01 Oct 2020 11:50:06

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T06:50:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '70b82ef1-b32c-4b79-8c09-48c9cb84393e' User entered 'None (1)'	System	01 Oct 2020 11:50:06
	System	01 Oct 2020 11:50:06

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T06:50:03', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '70b82ef1-b32c-4b79-8c09-48c9cb84393e' User entered '01 Oct 2020 06:50'	System	01 Oct 2020 11:50:06
	System	01 Oct 2020 11:50:06

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 4'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T21:07:45', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a645572f-9835-4db8-942e-1f1fefe22d4c' User entered 'None (1)'	System	02 Oct 2020 02:07:56
	System	02 Oct 2020 02:07:56

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T21:07:47', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a645572f-9835-4db8-942e-1f1fefe22d4c' User entered 'No (N)'	System	02 Oct 2020 02:07:56
	System	02 Oct 2020 02:07:56

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T21:07:49', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a645572f-9835-4db8-942e-1f1fefe22d4c' User entered 'No (N)'	System	02 Oct 2020 02:07:56
	System	02 Oct 2020 02:07:56

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T21:07:50', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a645572f-9835-4db8-942e-1f1fefe22d4c' User entered 'None (1)'	System	02 Oct 2020 02:07:56
	System	02 Oct 2020 02:07:56

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T21:07:53', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a645572f-9835-4db8-942e-1f1fefe22d4c' User entered '01 Oct 2020 21:07'	System	02 Oct 2020 02:07:56
	System	02 Oct 2020 02:07:56

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 5'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-02T19:39:43', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '4d57f7ad-ebfc-45be-bac8-bcbaa807fee9'	System	03 Oct 2020 00:40:01
User entered 'None (1)'	System	03 Oct 2020 00:40:01

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-02T19:39:49', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '4d57f7ad-ebfc-45be-bac8-bcbaa807fee9' User entered 'No (N)'	System	03 Oct 2020 00:40:01
	System	03 Oct 2020 00:40:01

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-02T19:39:50', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '4d57f7ad-ebfc-45be-bac8-bcbaa807fee9' User entered 'No (N)'	System	03 Oct 2020 00:40:01
	System	03 Oct 2020 00:40:01

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-02T19:39:52', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '4d57f7ad-ebfc-45be-bac8-bcbaa807fee9'	System	03 Oct 2020 00:40:01
User entered 'None (1)'	System	03 Oct 2020 00:40:01

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-02T19:39:55', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '4d57f7ad-ebfc-45be-bac8-bcbaa807fee9' User entered '02 Oct 2020 19:39'	System	03 Oct 2020 00:40:01
	System	03 Oct 2020 00:40:01

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 6'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T10:29:08', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'cc49b5dd-5af8-4805-bba6-caa5092a86e8'	System	04 Oct 2020 15:29:20
User entered 'None (1)'	System	04 Oct 2020 15:29:20

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T10:29:11', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'cc49b5dd-5af8-4805-bba6-caa5092a86e8' User entered 'No (N)'	System	04 Oct 2020 15:29:20
	System	04 Oct 2020 15:29:20

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T10:29:13', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'cc49b5dd-5af8-4805-bba6-caa5092a86e8' User entered 'No (N)'	System	04 Oct 2020 15:29:20
	System	04 Oct 2020 15:29:20

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T10:29:15', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'cc49b5dd-5af8-4805-bba6-caa5092a86e8'	System	04 Oct 2020 15:29:20
User entered 'None (1)'	System	04 Oct 2020 15:29:20

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T10:29:18', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'cc49b5dd-5af8-4805-bba6-caa5092a86e8' User entered '04 Oct 2020 10:29'	System	04 Oct 2020 15:29:20
	System	04 Oct 2020 15:29:20

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 7'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T22:09:19', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'df8f2b6e-1cae-4404-8443-711d1168234a' User entered 'None (1)'	System	05 Oct 2020 03:09:31
	System	05 Oct 2020 03:09:31

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T22:09:21', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'df8f2b6e-1cae-4404-8443-711d1168234a' User entered 'No (N)'	System	05 Oct 2020 03:09:31
	System	05 Oct 2020 03:09:31

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T22:09:22', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'df8f2b6e-1cae-4404-8443-711d1168234a' User entered 'No (N)'	System	05 Oct 2020 03:09:31
	System	05 Oct 2020 03:09:31

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T22:09:23', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'df8f2b6e-1cae-4404-8443-711d1168234a' User entered 'None (1)'	System	05 Oct 2020 03:09:31
	System	05 Oct 2020 03:09:31

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T22:09:27', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'df8f2b6e-1cae-4404-8443-711d1168234a' User entered '04 Oct 2020 22:09'	System	05 Oct 2020 03:09:31
	System	05 Oct 2020 03:09:31

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T09:01:18', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '34ada18d-57b1-45f8-81c7-5dba1150fd4b' User entered 'None (0)'	System	28 Sep 2020 14:01:37
	System	28 Sep 2020 14:01:37

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T09:01:21', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '34ada18d-57b1-45f8-81c7-5dba1150fd4b' User entered 'None (0)'	System	28 Sep 2020 14:01:37
	System	28 Sep 2020 14:01:37

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T09:01:23', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '34ada18d-57b1-45f8-81c7-5dba1150fd4b' User entered 'None (0)'	System	28 Sep 2020 14:01:37
	System	28 Sep 2020 14:01:37

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T09:01:24', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '34ada18d-57b1-45f8-81c7-5dba1150fd4b' User entered 'None (0)'	System	28 Sep 2020 14:01:37
	System	28 Sep 2020 14:01:37

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T09:01:26', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '34ada18d-57b1-45f8-81c7-5dba1150fd4b' User entered 'None (0)'	System	28 Sep 2020 14:01:37
	System	28 Sep 2020 14:01:37

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T09:01:28', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '34ada18d-57b1-45f8-81c7-5dba1150fd4b' User entered 'None (0)'	System	28 Sep 2020 14:01:37
	System	28 Sep 2020 14:01:37

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T09:01:30', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '34ada18d-57b1-45f8-81c7-5dba1150fd4b' User entered 'No (N)'	System	28 Sep 2020 14:01:37
	System	28 Sep 2020 14:01:37

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T09:01:35', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '34ada18d-57b1-45f8-81c7-5dba1150fd4b' User entered '28 Sep 2020 09:01'	System	28 Sep 2020 14:01:37
	System	28 Sep 2020 14:01:37

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '28 Sep 2020 08:46'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '28 Sep 2020 11:16'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T19:34:39', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'f42aa8f6-c7b9-4a3f-baf4-9fd1e31046ed'	System	29 Sep 2020 00:35:05
User entered 'No interference with activity (1)'	System	29 Sep 2020 00:35:05

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T19:34:42', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'f42aa8f6-c7b9-4a3f-baf4-9fd1e31046ed' User entered 'None (0)'	System	29 Sep 2020 00:35:05
	System	29 Sep 2020 00:35:05

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T19:34:45', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'f42aa8f6-c7b9-4a3f-baf4-9fd1e31046ed' User entered 'None (0)'	System	29 Sep 2020 00:35:05
	System	29 Sep 2020 00:35:05

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T19:34:47', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'f42aa8f6-c7b9-4a3f-baf4-9fd1e31046ed' User entered 'None (0)'	System	29 Sep 2020 00:35:05
	System	29 Sep 2020 00:35:05

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T19:34:49', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'f42aa8f6-c7b9-4a3f-baf4-9fd1e31046ed' User entered 'None (0)'	System	29 Sep 2020 00:35:05
	System	29 Sep 2020 00:35:05

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T19:34:52', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'f42aa8f6-c7b9-4a3f-baf4-9fd1e31046ed' User entered 'None (0)'	System	29 Sep 2020 00:35:05
	System	29 Sep 2020 00:35:05

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T19:34:56', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'f42aa8f6-c7b9-4a3f-baf4-9fd1e31046ed'	System	29 Sep 2020 00:35:05
User entered 'No (N)'	System	29 Sep 2020 00:35:05

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-28T19:35:02', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'f42aa8f6-c7b9-4a3f-baf4-9fd1e31046ed' User entered '28 Sep 2020 19:35'	System	29 Sep 2020 00:35:05
	System	29 Sep 2020 00:35:05

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '28 Sep 2020 12:11'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 2'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-29T23:47:27', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '37e45a8f-cb3d-43bc-9821-8e5e323ac5c0'	System	30 Sep 2020 04:47:53
User entered 'No interference with activity (1)'	System	30 Sep 2020 04:47:53

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-29T23:47:30', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '37e45a8f-cb3d-43bc-9821-8e5e323ac5c0' User entered 'None (0)'	System	30 Sep 2020 04:47:53
	System	30 Sep 2020 04:47:53

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-29T23:47:31', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '37e45a8f-cb3d-43bc-9821-8e5e323ac5c0' User entered 'None (0)'	System	30 Sep 2020 04:47:53
	System	30 Sep 2020 04:47:53

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-29T23:47:33', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '37e45a8f-cb3d-43bc-9821-8e5e323ac5c0' User entered 'None (0)'	System	30 Sep 2020 04:47:53
	System	30 Sep 2020 04:47:53

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-29T23:47:35', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '37e45a8f-cb3d-43bc-9821-8e5e323ac5c0' User entered 'None (0)'	System	30 Sep 2020 04:47:53
	System	30 Sep 2020 04:47:53

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-29T23:47:37', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '37e45a8f-cb3d-43bc-9821-8e5e323ac5c0' User entered 'None (0)'	System	30 Sep 2020 04:47:53
	System	30 Sep 2020 04:47:53

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-29T23:47:41', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '37e45a8f-cb3d-43bc-9821-8e5e323ac5c0'	System	30 Sep 2020 04:47:53
User entered 'No (N)'	System	30 Sep 2020 04:47:53

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-09-29T23:47:49', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '37e45a8f-cb3d-43bc-9821-8e5e323ac5c0' User entered '29 Sep 2020 23:47'	System	30 Sep 2020 04:47:53
	System	30 Sep 2020 04:47:53

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 3'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T06:50:14', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '353b9b4a-d0ff-44f1-8216-eadae8e12a8d'	System	01 Oct 2020 11:50:36
User entered 'No interference with activity (1)'	System	01 Oct 2020 11:50:36

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T06:50:16', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '353b9b4a-d0ff-44f1-8216-eadae8e12a8d' User entered 'None (0)'	System	01 Oct 2020 11:50:36
	System	01 Oct 2020 11:50:36

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T06:50:18', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '353b9b4a-d0ff-44f1-8216-eadae8e12a8d' User entered 'None (0)'	System	01 Oct 2020 11:50:36
	System	01 Oct 2020 11:50:36

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T06:50:19', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '353b9b4a-d0ff-44f1-8216-eadae8e12a8d' User entered 'None (0)'	System	01 Oct 2020 11:50:36
	System	01 Oct 2020 11:50:36

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T06:50:21', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '353b9b4a-d0ff-44f1-8216-eadae8e12a8d' User entered 'None (0)'	System	01 Oct 2020 11:50:36
	System	01 Oct 2020 11:50:36

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T06:50:22', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '353b9b4a-d0ff-44f1-8216-eadae8e12a8d' User entered 'None (0)'	System	01 Oct 2020 11:50:36
	System	01 Oct 2020 11:50:36

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T06:50:25', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '353b9b4a-d0ff-44f1-8216-eadae8e12a8d' User entered 'No (N)'	System	01 Oct 2020 11:50:36
	System	01 Oct 2020 11:50:36

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T06:50:30', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '353b9b4a-d0ff-44f1-8216-eadae8e12a8d' User entered '01 Oct 2020 06:50'	System	01 Oct 2020 11:50:36
	System	01 Oct 2020 11:50:36

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 4'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T21:07:57', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '22b4763b-a8ed-4b3b-a25e-99e781d8ee2b' User entered 'None (0)'	System	02 Oct 2020 02:08:13
	System	02 Oct 2020 02:08:13

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T21:07:59', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '22b4763b-a8ed-4b3b-a25e-99e781d8ee2b' User entered 'None (0)'	System	02 Oct 2020 02:08:13
	System	02 Oct 2020 02:08:13

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T21:08:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '22b4763b-a8ed-4b3b-a25e-99e781d8ee2b' User entered 'None (0)'	System	02 Oct 2020 02:08:13
	System	02 Oct 2020 02:08:13

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T21:08:01', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '22b4763b-a8ed-4b3b-a25e-99e781d8ee2b' User entered 'None (0)'	System	02 Oct 2020 02:08:13
	System	02 Oct 2020 02:08:13

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T21:08:03', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '22b4763b-a8ed-4b3b-a25e-99e781d8ee2b' User entered 'None (0)'	System	02 Oct 2020 02:08:13
	System	02 Oct 2020 02:08:13

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T21:08:05', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '22b4763b-a8ed-4b3b-a25e-99e781d8ee2b' User entered 'None (0)'	System	02 Oct 2020 02:08:13
	System	02 Oct 2020 02:08:13

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T21:08:06', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '22b4763b-a8ed-4b3b-a25e-99e781d8ee2b' User entered 'No (N)'	System	02 Oct 2020 02:08:13
	System	02 Oct 2020 02:08:13

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-01T21:08:10', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '22b4763b-a8ed-4b3b-a25e-99e781d8ee2b' User entered '01 Oct 2020 21:08'	System	02 Oct 2020 02:08:13
	System	02 Oct 2020 02:08:13

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 5'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-02T19:39:58', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a4d793dc-a206-4e9c-9549-a6c67a1d17b3' User entered 'None (0)'	System	03 Oct 2020 00:40:17
	System	03 Oct 2020 00:40:17

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-02T19:40:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a4d793dc-a206-4e9c-9549-a6c67a1d17b3' User entered 'None (0)'	System	03 Oct 2020 00:40:17
	System	03 Oct 2020 00:40:17

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-02T19:40:01', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a4d793dc-a206-4e9c-9549-a6c67a1d17b3' User entered 'None (0)'	System	03 Oct 2020 00:40:17
	System	03 Oct 2020 00:40:17

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-02T19:40:02', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a4d793dc-a206-4e9c-9549-a6c67a1d17b3' User entered 'None (0)'	System	03 Oct 2020 00:40:17
	System	03 Oct 2020 00:40:17

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-02T19:40:04', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a4d793dc-a206-4e9c-9549-a6c67a1d17b3' User entered 'None (0)'	System	03 Oct 2020 00:40:17
	System	03 Oct 2020 00:40:17

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-02T19:40:05', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a4d793dc-a206-4e9c-9549-a6c67a1d17b3' User entered 'None (0)'	System	03 Oct 2020 00:40:17
	System	03 Oct 2020 00:40:17

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-02T19:40:07', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a4d793dc-a206-4e9c-9549-a6c67a1d17b3' User entered 'No (N)'	System	03 Oct 2020 00:40:17
	System	03 Oct 2020 00:40:17

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-02T19:40:12', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a4d793dc-a206-4e9c-9549-a6c67a1d17b3' User entered '02 Oct 2020 19:40'	System	03 Oct 2020 00:40:17
	System	03 Oct 2020 00:40:17

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 6'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T10:29:21', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '59b2c04c-e123-4ec5-acde-c93c13846304' User entered 'None (0)'	System	04 Oct 2020 15:29:39
	System	04 Oct 2020 15:29:39

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T10:29:23', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '59b2c04c-e123-4ec5-acde-c93c13846304' User entered 'None (0)'	System	04 Oct 2020 15:29:39
	System	04 Oct 2020 15:29:39

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T10:29:24', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '59b2c04c-e123-4ec5-acde-c93c13846304' User entered 'None (0)'	System	04 Oct 2020 15:29:39
	System	04 Oct 2020 15:29:39

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T10:29:25', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '59b2c04c-e123-4ec5-acde-c93c13846304' User entered 'None (0)'	System	04 Oct 2020 15:29:39
	System	04 Oct 2020 15:29:39

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T10:29:27', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '59b2c04c-e123-4ec5-acde-c93c13846304' User entered 'None (0)'	System	04 Oct 2020 15:29:39
	System	04 Oct 2020 15:29:39

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T10:29:28', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '59b2c04c-e123-4ec5-acde-c93c13846304' User entered 'None (0)'	System	04 Oct 2020 15:29:39
	System	04 Oct 2020 15:29:39

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T10:29:32', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '59b2c04c-e123-4ec5-acde-c93c13846304' User entered 'No (N)'	System	04 Oct 2020 15:29:39
	System	04 Oct 2020 15:29:39

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T10:29:34', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '59b2c04c-e123-4ec5-acde-c93c13846304' User entered '04 Oct 2020 10:29'	System	04 Oct 2020 15:29:39
	System	04 Oct 2020 15:29:39

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	28 Sep 2020 14:00:19
User entered 'Day 7'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T22:09:30', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '065282cb-0078-474b-ad94-27f4fc19887c' User entered 'None (0)'	System	05 Oct 2020 03:09:49
	System	05 Oct 2020 03:09:49

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T22:09:32', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '065282cb-0078-474b-ad94-27f4fc19887c' User entered 'None (0)'	System	05 Oct 2020 03:09:49
	System	05 Oct 2020 03:09:49

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T22:09:33', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '065282cb-0078-474b-ad94-27f4fc19887c' User entered 'None (0)'	System	05 Oct 2020 03:09:49
	System	05 Oct 2020 03:09:49

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T22:09:34', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '065282cb-0078-474b-ad94-27f4fc19887c' User entered 'None (0)'	System	05 Oct 2020 03:09:49
	System	05 Oct 2020 03:09:49

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T22:09:36', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '065282cb-0078-474b-ad94-27f4fc19887c' User entered 'None (0)'	System	05 Oct 2020 03:09:49
	System	05 Oct 2020 03:09:49

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T22:09:37', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '065282cb-0078-474b-ad94-27f4fc19887c' User entered 'None (0)'	System	05 Oct 2020 03:09:49
	System	05 Oct 2020 03:09:49

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T22:09:39', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '065282cb-0078-474b-ad94-27f4fc19887c' User entered 'No (N)'	System	05 Oct 2020 03:09:49
	System	05 Oct 2020 03:09:49

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-10-04T22:09:44', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '065282cb-0078-474b-ad94-27f4fc19887c' User entered '04 Oct 2020 22:09'	System	05 Oct 2020 03:09:49
	System	05 Oct 2020 03:09:49

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 14:00:19

US3252399

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 14:00:19

US3252399

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:04
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	06 Oct 2020 03:43:32
	(b) (4)	

US3252399

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:04
User entered '5 Oct 2020'	Nancy Torrence (b) (4)	06 Oct 2020 03:43:32
	(b) (4)	

US3252399

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:04
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	06 Oct 2020 03:43:32
	(b) (4)	

US3252399

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:04
User entered empty.	Nancy Torrence (b) (4)	06 Oct 2020 03:43:32
	(b) (4)	

US3252399

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:04
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	06 Oct 2020 03:43:39
	(b) (4)	

US3252399

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'I'	System	06 Oct 2020 03:43:39

US3252399

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	13 Oct 2020 04:13:23
	(b) (4)	

US3252399

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '12 Oct 2020'	Nancy Torrence (b) (4)	13 Oct 2020 04:13:23
	(b) (4)	

US3252399

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	13 Oct 2020 04:13:23
	(b) (4)	

US3252399

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Nancy Torrence (b) (4)	13 Oct 2020 04:13:23
	(b) (4)	

US3252399

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	13 Oct 2020 04:13:27
	(b) (4)	

US3252399

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'I'	System	13 Oct 2020 04:13:27

US3252399

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	21 Oct 2020 07:39:43
	(b) (4)	

US3252399

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '19 Oct 2020'	Nancy Torrence (b) (4)	21 Oct 2020 07:39:43
	(b) (4)	

US3252399

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	21 Oct 2020 07:39:43
	(b) (4)	

US3252399

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Nancy Torrence (b) (4)	21 Oct 2020 07:39:43
	(b) (4)	

US3252399

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	21 Oct 2020 07:39:48
	(b) (4)	

US3252399

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'I'	System	21 Oct 2020 07:39:48

US3252399

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	31 Oct 2020 07:46:04
	(b) (4)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '30 Oct 2020'	Nancy Torrence (b) (4)	31 Oct 2020 07:46:04
	(b) (4)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[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 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Clinic (Clinic)'	Nancy Torrence (b) (4)	31 Oct 2020 07:46:04
	(b) (4)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'VISIT3'	System	31 Oct 2020 07:46:04

US3252399

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	31 Oct 2020 07:47:21
	(b) (4)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '30 Oct 2020'	Nancy Torrence (b) (4)	31 Oct 2020 07:47:21
	(b) (4)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '08:35'	Nancy Torrence (b) (4)	31 Oct 2020 07:47:21
	(b) (4)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered '30 Oct 2020 08:35'	System	31 Oct 2020 07:47:21

US3252399

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '98.7' F	Nancy Torrence (b) (4)	31 Oct 2020 07:47:21
	(b) (4)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Oral (Oral)'	Nancy Torrence (b) (4)	31 Oct 2020 07:47:21
	(b) (4)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Nancy Torrence (b) (4)	31 Oct 2020 07:47:21
	(b) (4)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '87'	Nancy Torrence (b) (4)	31 Oct 2020 07:47:21
	(b) (4)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'bpm'	System	31 Oct 2020 07:47:21

US3252399

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '16'	Nancy Torrence (b) (4)	31 Oct 2020 07:47:21
	(b) (4)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'breaths/min'	System	31 Oct 2020 07:47:21

US3252399

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '123'	Nancy Torrence (b) (4)	31 Oct 2020 07:47:21
	(b) (4)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'mmHg'	System	31 Oct 2020 07:47:21

US3252399

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '87'	Nancy Torrence (b) (4)	31 Oct 2020 07:47:21
	(b) (4)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'mmHg'	System	31 Oct 2020 07:47:21

US3252399

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08

US3252399

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08

US3252399

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'No (N)'	Nancy Torrence (b) (4)	31 Oct 2020 07:47:29
	(b) (4)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered empty.	Nancy Torrence (b) (4)	31 Oct 2020 07:47:29
	(b) (4)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	31 Oct 2020 07:47:51
	(b) (4)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '30 Oct 2020'	Nancy Torrence (b) (4)	31 Oct 2020 07:47:51
	(b) (4)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered '08:41'	Nancy Torrence (b) (4)	31 Oct 2020 07:47:51
	(b) (4)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered '30 Oct 2020 08:41'	System	31 Oct 2020 07:47:51

US3252399

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 02:18:07
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	31 Oct 2020 07:47:59
	(b) (4)	

US3252399

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'I'	System	31 Oct 2020 07:47:59

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 64'	System	01 Sep 2020 13:46:41

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-11-03T18:05:43', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '8ad3356c-1d40-4cf5-9100-b0ae39cc983a' User entered 'No (N)'	System	04 Nov 2020 00:06:06
	System	04 Nov 2020 00:06:06

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-11-03T18:05:48', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '8ad3356c-1d40-4cf5-9100-b0ae39cc983a' User entered 'No (N)'	System	04 Nov 2020 00:06:06
	System	04 Nov 2020 00:06:06

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-11-03T18:06:03', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '8ad3356c-1d40-4cf5-9100-b0ae39cc983a' User entered '03 Nov 2020 18:06:03'	System	04 Nov 2020 00:06:06
	System	04 Nov 2020 00:06:06

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 13:46:41

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 71'	System	01 Sep 2020 13:46:41

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-11-09T18:01:46', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'c51b76d5-2d7a-48b2-9f11-1ece170bdb20' User entered 'No (N)'	System	10 Nov 2020 00:02:04
	System	10 Nov 2020 00:02:04

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-11-09T18:01:53', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'c51b76d5-2d7a-48b2-9f11-1ece170bdb20'	System	10 Nov 2020 00:02:04
User entered 'No (N)'	System	10 Nov 2020 00:02:04

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-11-09T18:01:59', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'c51b76d5-2d7a-48b2-9f11-1ece170bdb20' User entered '09 Nov 2020 18:01:59'	System	10 Nov 2020 00:02:04
	System	10 Nov 2020 00:02:04

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 13:46:41

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered 'Day 78'	System	01 Sep 2020 13:46:41

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-11-16T08:21:16', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'ab21d111-c817-4659-9731-4ecd8b3bb89e' User entered 'No (N)'	System	16 Nov 2020 14:21:35
	System	16 Nov 2020 14:21:35

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-11-16T08:21:20', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'ab21d111-c817-4659-9731-4ecd8b3bb89e' User entered 'No (N)'	System	16 Nov 2020 14:21:35
	System	16 Nov 2020 14:21:35

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-11-16T08:21:32', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'ab21d111-c817-4659-9731-4ecd8b3bb89e' User entered '16 Nov 2020 08:21:32'	System	16 Nov 2020 14:21:35
	System	16 Nov 2020 14:21:35

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 13:46:41

US3252399

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:08
Data entry locked.	System	01 Sep 2020 13:46:41
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 13:46:41

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-11-23T11:18:31', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '23d08ec0-b8e2-427f-9b6a-64b620dd61b9'	System	23 Nov 2020 17:18:48
User entered 'No (N)'	System	23 Nov 2020 17:18:48

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Have you been exposed to someone with 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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-11-23T11:18:34', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '23d08ec0-b8e2-427f-9b6a-64b620dd61b9' User entered 'No (N)'	System	23 Nov 2020 17:18:48

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-11-23T11:18:44', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '23d08ec0-b8e2-427f-9b6a-64b620dd61b9' User entered '23 Nov 2020 11:18:44'	System	23 Nov 2020 17:18:48
	System	23 Nov 2020 17:18:48

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-11-30T12:42:10', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a6cc7925-8f86-44b0-b823-00b2e2d6e009' User entered 'No (N)'	System	30 Nov 2020 18:42:26

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-11-30T12:41:49', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a6cc7925-8f86-44b0-b823-00b2e2d6e009'	System	30 Nov 2020 18:42:26
User entered 'No (N)'	System	30 Nov 2020 18:42:26

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-11-30T12:42:20', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a6cc7925-8f86-44b0-b823-00b2e2d6e009'	System	30 Nov 2020 18:42:26
User entered '30 Nov 2020 12:42:20'	System	30 Nov 2020 18:42:26

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-12-07T17:57:28', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '26f657ab-a7f8-4cfd-a9a2-1513ade8b709'	System	07 Dec 2020 23:57:41
User entered 'No (N)'	System	07 Dec 2020 23:57:41

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-12-07T17:57:32', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '26f657ab-a7f8-4cfd-a9a2-1513ade8b709'	System	07 Dec 2020 23:57:41
User entered 'No (N)'	System	07 Dec 2020 23:57:41

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-12-07T17:57:35', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '26f657ab-a7f8-4cfd-a9a2-1513ade8b709' User entered '07 Dec 2020 17:57:35'	System	07 Dec 2020 23:57:41
	System	07 Dec 2020 23:57:41

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-12-20T07:25:05', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '7bb7f28c-2425-4219-bb40-39496f2fc4d1' User entered 'No (N)'	System	20 Dec 2020 13:25:15
	System	20 Dec 2020 13:25:15

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Have you been exposed to someone with 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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-12-20T07:25:08', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '7bb7f28c-2425-4219-bb40-39496f2fc4d1' User entered 'No (N)'	System	20 Dec 2020 13:25:15
	System	20 Dec 2020 13:25:15

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-12-20T07:25:11', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '7bb7f28c-2425-4219-bb40-39496f2fc4d1' User entered '20 Dec 2020 07:25:11'	System	20 Dec 2020 13:25:15
	System	20 Dec 2020 13:25:15

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-12-28T07:42:26', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '95adfad2-0a64-4219-bafb-e9af642ce4aa' User entered 'No (N)'	System	28 Dec 2020 13:42:44

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-12-28T07:42:39', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '95adfad2-0a64-4219-bafb-e9af642ce4aa' User entered 'No (N)'	System	28 Dec 2020 13:42:44

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2020-12-28T07:42:42', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '95adfad2-0a64-4219-bafb-e9af642ce4aa' User entered '28 Dec 2020 07:42:42'	System	28 Dec 2020 13:42:44
	System	28 Dec 2020 13:42:44

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-01-03T18:54:15', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '48b2e869-aaa3-44e2-ba0a-87c86f075888'	System	04 Jan 2021 00:54:24
User entered 'No (N)'	System	04 Jan 2021 00:54:24

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-01-03T18:54:18', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '48b2e869-aaa3-44e2-ba0a-87c86f075888'	System	04 Jan 2021 00:54:24
User entered 'No (N)'	System	04 Jan 2021 00:54:24

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-01-03T18:54:21', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '48b2e869-aaa3-44e2-ba0a-87c86f075888' User entered '03 Jan 2021 18:54:21'	System	04 Jan 2021 00:54:24
	System	04 Jan 2021 00:54:24

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-01-10T07:45:23', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'bc102b30-9754-45a2-a988-d406484d43ed' User entered 'No (N)'	System	10 Jan 2021 13:45:34

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-01-10T07:45:27', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'bc102b30-9754-45a2-a988-d406484d43ed'	System	10 Jan 2021 13:45:34
User entered 'No (N)'	System	10 Jan 2021 13:45:34

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-01-10T07:45:31', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'bc102b30-9754-45a2-a988-d406484d43ed' User entered '10 Jan 2021 07:45:31'	System	10 Jan 2021 13:45:34

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-01-17T01:33:41', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '415b46f3-efb5-4ee4-9c6c-19fcddabdd18'	System	17 Jan 2021 07:33:53
User entered 'No (N)'	System	17 Jan 2021 07:33:53

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-01-17T01:33:44', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '415b46f3-efb5-4ee4-9c6c-19fcddabdd18'	System	17 Jan 2021 07:33:53
User entered 'No (N)'	System	17 Jan 2021 07:33:53

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-01-17T01:33:49', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '415b46f3-efb5-4ee4-9c6c-19fcddabdd18'	System	17 Jan 2021 07:33:53
User entered '17 Jan 2021 01:33:49'	System	17 Jan 2021 07:33:53

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-01-23T17:25:27', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '24166c38-9a6e-4d3b-9ed1-e796dfe7d372' User entered 'No (N)'	System	23 Jan 2021 23:25:43
	System	23 Jan 2021 23:25:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-01-23T17:25:35', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '24166c38-9a6e-4d3b-9ed1-e796dfe7d372'	System	23 Jan 2021 23:25:43
User entered 'No (N)'	System	23 Jan 2021 23:25:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-01-23T17:25:38', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '24166c38-9a6e-4d3b-9ed1-e796dfe7d372' User entered '23 Jan 2021 17:25:38'	System	23 Jan 2021 23:25:43
	System	23 Jan 2021 23:25:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-01-30T12:00:27', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'cdf5e0ac-8a22-4e24-a5c6-e35499f98246'	System	30 Jan 2021 18:00:54
User entered 'No (N)'	System	30 Jan 2021 18:00:54

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-01-30T12:00:30', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'cdf5e0ac-8a22-4e24-a5c6-e35499f98246'	System	30 Jan 2021 18:00:54
User entered 'No (N)'	System	30 Jan 2021 18:00:54

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-01-30T12:00:33', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'cdf5e0ac-8a22-4e24-a5c6-e35499f98246' User entered '30 Jan 2021 12:00:33'	System	30 Jan 2021 18:00:54
	System	30 Jan 2021 18:00:54

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-02-07T19:18:42', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '8edb57f1-fa42-4bc5-9864-263e2a3f09e7'	System	08 Feb 2021 01:18:51
User entered 'No (N)'	System	08 Feb 2021 01:18:51

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-02-07T19:18:46', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '8edb57f1-fa42-4bc5-9864-263e2a3f09e7'	System	08 Feb 2021 01:18:51
User entered 'No (N)'	System	08 Feb 2021 01:18:51

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-02-07T19:18:49', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '8edb57f1-fa42-4bc5-9864-263e2a3f09e7' User entered '07 Feb 2021 19:18:49'	System	08 Feb 2021 01:18:51
	System	08 Feb 2021 01:18:51

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-02-13T13:16:41', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '36238e03-ac8d-4f7b-9b77-1c8e8ed7339e' User entered 'No (N)'	System	13 Feb 2021 19:16:59
	System	13 Feb 2021 19:16:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-02-13T13:16:46', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '36238e03-ac8d-4f7b-9b77-1c8e8ed7339e' User entered 'No (N)'	System	13 Feb 2021 19:16:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-02-13T13:16:56', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '36238e03-ac8d-4f7b-9b77-1c8e8ed7339e' User entered '13 Feb 2021 13:16:56'	System	13 Feb 2021 19:16:59
	System	13 Feb 2021 19:16:59

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-02-21T08:59:14', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '76e08eda-1c03-4437-a3e6-2ee4582560bb' User entered 'No (N)'	System	21 Feb 2021 14:59:22
	System	21 Feb 2021 14:59:22

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-02-21T08:59:17', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '76e08eda-1c03-4437-a3e6-2ee4582560bb' User entered 'No (N)'	System	21 Feb 2021 14:59:22
	System	21 Feb 2021 14:59:22

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-02-21T08:59:20', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '76e08eda-1c03-4437-a3e6-2ee4582560bb' User entered '21 Feb 2021 08:59:20'	System	21 Feb 2021 14:59:22
	System	21 Feb 2021 14:59:22

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-02-27T10:43:00-06:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '7439e110-ace2-4f08-88e9-9bb2849823d0' User entered 'No (N)'	System	27 Feb 2021 16:43:13
	System	27 Feb 2021 16:43:13

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Have you been exposed to someone with 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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-02-27T10:43:03-06:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '7439e110-ace2-4f08-88e9-9bb2849823d0' User entered 'No (N)'	System	27 Feb 2021 16:43:13
	System	27 Feb 2021 16:43:13

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-02-27T10:43:11-06:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '7439e110-ace2-4f08-88e9-9bb2849823d0' User entered '27 Feb 2021 16:43:11'	System	27 Feb 2021 16:43:13

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-03-06T15:07:44-06:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '79ccf929-8d22-449f-acae-ca3425d1b50a'	System	06 Mar 2021 21:08:20
User entered 'No (N)'	System	06 Mar 2021 21:08:20

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-03-06T15:07:47-06:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '79ccf929-8d22-449f-acae-ca3425d1b50a'	System	06 Mar 2021 21:08:20
User entered 'No (N)'	System	06 Mar 2021 21:08:20

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-03-06T15:08:16-06:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '79ccf929-8d22-449f-acae-ca3425d1b50a' User entered '06 Mar 2021 15:08:16'	System	06 Mar 2021 21:08:20
	System	06 Mar 2021 21:08:20

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-03-13T16:38:55-06:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a105e7cf-09e8-4359-9271-04f6c08bf3e0'	System	13 Mar 2021 22:40:24
User entered 'Yes (Y)'	System	13 Mar 2021 22:40:24

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-03-13T16:38:43-06:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a105e7cf-09e8-4359-9271-04f6c08bf3e0'	System	13 Mar 2021 22:40:24
User entered 'No (N)'	System	13 Mar 2021 22:40:24

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-03-13T16:38:42-06:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a105e7cf-09e8-4359-9271-04f6c08bf3e0'	System	13 Mar 2021 22:40:24
User entered 'No (N)'	System	13 Mar 2021 22:40:24

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-03-13T16:39:16-06:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a105e7cf-09e8-4359-9271-04f6c08bf3e0'	System	13 Mar 2021 22:40:24
User entered 'No (N)'	System	13 Mar 2021 22:40:24

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-03-13T16:40:22-06:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a105e7cf-09e8-4359-9271-04f6c08bf3e0'	System	13 Mar 2021 22:40:24
User entered '13 Mar 2021 16:40:22'	System	13 Mar 2021 22:40:24

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-03-19T15:25:57-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a8f5af51-1e43-405f-911f-920d55d15e25'	System	23 Mar 2021 15:46:40
User entered 'No (N)'	System	23 Mar 2021 15:46:40

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-03-19T15:25:59-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a8f5af51-1e43-405f-911f-920d55d15e25'	System	23 Mar 2021 15:46:40
User entered 'No (N)'	System	23 Mar 2021 15:46:40

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-03-19T15:26:02-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'a8f5af51-1e43-405f-911f-920d55d15e25'	System	23 Mar 2021 15:46:40
User entered '19 Mar 2021 15:26:02'	System	23 Mar 2021 15:46:40

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-03-27T23:00:59-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '6c29232a-7611-46f7-8592-182c960eeb06'	System	28 Mar 2021 04:01:38
User entered 'No (N)'	System	28 Mar 2021 04:01:38

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-03-27T23:01:03-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '6c29232a-7611-46f7-8592-182c960eeb06'	System	28 Mar 2021 04:01:38
User entered 'No (N)'	System	28 Mar 2021 04:01:38

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-03-27T23:01:05-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '6c29232a-7611-46f7-8592-182c960eeb06'	System	28 Mar 2021 04:01:38
User entered '27 Mar 2021 23:01:05'	System	28 Mar 2021 04:01:38

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-04-03T12:33:19-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'b380b057-c4d1-4c39-bdd2-ecf75419aa80'	System	03 Apr 2021 17:33:28
User entered 'No (N)'	System	03 Apr 2021 17:33:28

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-04-03T12:33:23-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'b380b057-c4d1-4c39-bdd2-ecf75419aa80'	System	03 Apr 2021 17:33:28
User entered 'No (N)'	System	03 Apr 2021 17:33:28

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-04-03T12:33:25-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'b380b057-c4d1-4c39-bdd2-ecf75419aa80'	System	03 Apr 2021 17:33:28
User entered '03 Apr 2021 12:33:25'	System	03 Apr 2021 17:33:28

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-04-11T14:45:53-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'da308c72-f0c5-4dc7-9321-4e83d9560237'	System	11 Apr 2021 19:46:00
User entered 'No (N)'	System	11 Apr 2021 19:46:00

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-04-11T14:45:55-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'da308c72-f0c5-4dc7-9321-4e83d9560237'	System	11 Apr 2021 19:46:00
User entered 'No (N)'	System	11 Apr 2021 19:46:00

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-04-11T14:45:57-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'da308c72-f0c5-4dc7-9321-4e83d9560237'	System	11 Apr 2021 19:46:00
User entered '11 Apr 2021 14:45:57'	System	11 Apr 2021 19:46:00

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-04-17T12:01:14-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '4eec393e-b985-45de-bb9d-5e2dfb841385' User entered 'No (N)'	System	17 Apr 2021 17:02:10
	System	17 Apr 2021 17:02:10

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-04-17T12:01:16-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '4eec393e-b985-45de-bb9d-5e2dfb841385'	System	17 Apr 2021 17:02:10
User entered 'No (N)'	System	17 Apr 2021 17:02:10

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-04-17T12:01:19-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '4eec393e-b985-45de-bb9d-5e2dfb841385'	System	17 Apr 2021 17:02:10
User entered '17 Apr 2021 12:01:19'	System	17 Apr 2021 17:02:10

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-04-25T18:03:15-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'ff490ad5-01be-4a3d-90f9-128d5dcb8884'	System	25 Apr 2021 23:05:31
User entered 'No (N)'	System	25 Apr 2021 23:05:31

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Have you been exposed to someone with 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 (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-04-25T18:03:18-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'ff490ad5-01be-4a3d-90f9-128d5dcb8884'	System	25 Apr 2021 23:05:31
User entered 'No (N)'	System	25 Apr 2021 23:05:31

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-04-25T18:03:20-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'ff490ad5-01be-4a3d-90f9-128d5dcb8884'	System	25 Apr 2021 23:05:31
User entered '25 Apr 2021 18:03:20'	System	25 Apr 2021 23:05:31

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[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 (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-05-02T11:09:11-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '54d6fa03-3901-467e-bd19-ce36bafbb2a7'	System	02 May 2021 16:12:09
User entered 'No (N)'	System	02 May 2021 16:12:09

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

Have you been exposed to someone with 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 (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-05-02T11:09:15-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '54d6fa03-3901-467e-bd19-ce36bafbb2a7'	System	02 May 2021 16:12:09
User entered 'No (N)'	System	02 May 2021 16:12:09

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2923E90F-D967-4C57-ADD8-F9238740B20A)', Time: '2021-05-02T11:09:42-05:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: '54d6fa03-3901-467e-bd19-ce36bafbb2a7'	System	02 May 2021 16:12:09
User entered '02 May 2021 11:09:42'	System	02 May 2021 16:12:09

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 21:30:43

US3252399

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:30:43
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 21:30:43

US3252399

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:14:00

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 16:17:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-02-27T10:42:37-06:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'b0f69fdf-f937-4450-ad0c-2fe66c20f3a4'	System	27 Feb 2021 16:42:48
User entered 'No (N)'	System	27 Feb 2021 16:42:48

US3252399

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:14:00

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:17:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDA47B5E-D564-411D-8576-964134B3F87C)', Time: '2021-02-27T10:42:46-06:00', User OID: 'PatientReportedOutcome (US3252399)', ODM File OID: 'b0f69fdf-f937-4450-ad0c-2fe66c20f3a4'	System	27 Feb 2021 16:42:48
User entered '27 Feb 2021 16:42:46'	System	27 Feb 2021 16:42:48

US3252399

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	24 Nov 2020 03:53:23
	(b) (4)	

US3252399

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '23 Nov 2020'	Shannon Moyer (b) (4)	24 Nov 2020 03:53:23
	(b) (4)	

US3252399

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	24 Nov 2020 03:53:23
	(b) (4)	

US3252399

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Shannon Moyer (b) (4)	24 Nov 2020 03:53:23
	(b) (4)	

US3252399

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	24 Nov 2020 03:53:27
	(b) (4)	

US3252399

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:57:08
User entered 'I'	System	24 Nov 2020 03:53:27

US3252399

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	30 Dec 2020 02:23:28
	(b) (4)	

US3252399

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '29 Dec 2020'	Shannon Moyer (b) (4)	30 Dec 2020 02:23:28
	(b) (4)	

US3252399

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	30 Dec 2020 02:23:28
	(b) (4)	

US3252399

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Shannon Moyer (b) (4)	30 Dec 2020 02:23:28
	(b) (4)	

US3252399

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	30 Dec 2020 02:23:33
	(b) (4)	

US3252399

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User entered 'I'	System	30 Dec 2020 02:23:33

US3252399

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Joanna Gurrola Mahoney	28 Jan 2021 02:53:45
	(b) (4)	

US3252399

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '26 Jan 2021'	Joanna Gurrola Mahoney (b) (4)	28 Jan 2021 02:53:45

US3252399

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Contact Made (CONTACT MADE)'	Joanna Gurrola Mahoney (b) (4)	28 Jan 2021 02:53:45

US3252399

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Joanna Gurrola Mahoney (b) (4)	28 Jan 2021 02:53:45

US3252399

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	28 Jan 2021 02:53:50

US3252399

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User entered 'I'	System	28 Jan 2021 02:53:50

US3252399

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 02:40:01

US3252399

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '25 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 02:40:01

US3252399

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Feb 2021 02:40:01

US3252399

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 02:40:01

US3252399

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 02:40:07

US3252399

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User entered 'I'	System	26 Feb 2021 02:40:07

US3252399

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 02:50:06

US3252399

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered '26 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 02:50:06

US3252399

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[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 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	29 Mar 2021 02:50:06

US3252399

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User entered 'VISIT4'	System	29 Mar 2021 02:50:06

US3252399

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 06:55:32

US3252399

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 06:55:32

US3252399

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 06:55:32

US3252399

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User entered empty.	System	29 Mar 2021 06:55:32

US3252399

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 06:55:32

US3252399

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 06:55:32

US3252399

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 06:55:32

US3252399

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 06:55:32

US3252399

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User entered empty.	System	29 Mar 2021 06:55:32

US3252399

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 06:55:32

US3252399

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User entered empty.	System	29 Mar 2021 06:55:32

US3252399

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 06:55:32

US3252399

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User entered empty.	System	29 Mar 2021 06:55:32

US3252399

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 06:55:32

US3252399

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User entered empty.	System	29 Mar 2021 06:55:32

US3252399

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57

US3252399

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57

US3252399

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 03:00:41

US3252399

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:00

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 03:00:41

US3252399

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 03:00:59

US3252399

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered '26 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 03:00:59

US3252399

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered '07:44'	(b) (4), (b) (6)	29 Mar 2021 03:00:59

US3252399

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User entered '26 Mar 2021 07:44'	System	29 Mar 2021 03:00:59

US3252399

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 03:01:05

US3252399

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:44:57
User entered 'I'	System	29 Mar 2021 03:01:05

US3252399

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

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	23 Jan 2021 04:31:51
	(b) (4)	

US3252399

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

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '22 Jan 2021'	Shannon Moyer (b) (4)	23 Jan 2021 04:31:51
	(b) (4)	

US3252399

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

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[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 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4)	23 Jan 2021 04:31:51
	(b) (4)	

US3252399

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

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'UNBLND_DECIDE'	System	23 Jan 2021 04:31:51

US3252399

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:00

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '22 Jan 2021'	Shannon Moyer (b) (4)	23 Jan 2021 04:32:06
	(b) (4)	

US3252399

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:00

[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 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:44:44

US3252399

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:00

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	23 Jan 2021 04:32:06
	(b) (4)	

US3252399

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:00

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
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 07:44:44

US3252399

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:00

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '22 Jan 2021'	Shannon Moyer (b) (4)	23 Jan 2021 04:32:06
	(b) (4)	

US3252399

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:00

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Placebo (Placebo)'	Shannon Moyer (b) (4)	23 Jan 2021 04:32:06
	(b) (4)	

US3252399

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:00

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Placebo (Placebo)'	Shannon Moyer (b) (4)	23 Jan 2021 04:32:06
	(b) (4)	

US3252399

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:00

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Placebo (Placebo)'	Shannon Moyer (b) (4)	23 Jan 2021 04:32:06
	(b) (4)	

US3252399

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:00

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	23 Jan 2021 04:32:06
	(b) (4)	

US3252399

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:00

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '1'	System	23 Jan 2021 04:32:06

US3252399

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:00

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'I'	System	23 Jan 2021 04:32:06

US3252399

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:00

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:00

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:00

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered empty.	System	23 Jan 2021 04:34:04
DataPoint set to visible.	System	23 Jan 2021 04:32:06

US3252399

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:00

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:00

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:00

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered empty.	System	23 Jan 2021 04:34:04
DataPoint set to visible.	System	23 Jan 2021 04:32:06

US3252399

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:34:04

US3252399

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '22 Jan 2021'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '07:32'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '22 Jan 2021 07:32'	System	23 Jan 2021 04:34:04

US3252399

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '98.2' F	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '76'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'bpm'	System	23 Jan 2021 04:34:04

US3252399

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '15'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'breaths/min'	System	23 Jan 2021 04:34:04

US3252399

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '115'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'mmHg'	System	23 Jan 2021 04:34:04

US3252399

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '80'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'mmHg'	System	23 Jan 2021 04:34:04

US3252399

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:00

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:00

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:00

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered empty.	System	23 Jan 2021 04:34:04
DataPoint set to visible.	System	23 Jan 2021 04:32:06

US3252399

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	23 Jan 2021 04:34:04

US3252399

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '22 Jan 2021'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '08:41'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '22 Jan 2021 08:41'	System	23 Jan 2021 04:34:04

US3252399

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '97.1' F	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '79'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'bpm'	System	23 Jan 2021 04:34:04

US3252399

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '14'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'breaths/min'	System	23 Jan 2021 04:34:04

US3252399

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '118'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'mmHg'	System	23 Jan 2021 04:34:04

US3252399

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '88'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:04
	(b) (4)	

US3252399

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'mmHg'	System	23 Jan 2021 04:34:04

US3252399

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'No (N)'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:14
	(b) (4)	

US3252399

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Shannon Moyer (b) (4)	23 Jan 2021 04:34:14
	(b) (4)	

US3252399

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

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:08:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:33
	(b) (4)	

US3252399

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

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:08:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Shannon Moyer (b) (4)	23 Jan 2021 04:34:33
	(b) (4)	

US3252399

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

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

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)	30 Apr 2021 08:08:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Shannon Moyer (b) (4)	23 Jan 2021 04:34:33
	(b) (4)	

US3252399

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

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:08:40
User entered 'mRNA-1273'	System	23 Jan 2021 04:34:33
DataPoint set to visible.	System	23 Jan 2021 04:32:06

US3252399

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

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:08:40
User closed query 'Per CDMRQ: please review date in IRT and update accordingly' (Site from DM).		29 Apr 2021 07:16:01
Query 'Per CDMRQ: please review date in IRT and update accordingly' answered with 'the unblinding was performed on 22JAN2021' (Site from DM).		19 Apr 2021 02:55:30
User opened query 'Per CDMRQ: please review date in IRT and update accordingly' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 15:16:52
User closed query 'Per CDM, per sponsor review: Per IRT, Subject had Open Label Day1 Treatment on 19FEB2021. Please review and reconcile.' (Site from DM).		15 Apr 2021 15:16:52
Query 'Per CDM, per sponsor review: Per IRT, Subject had Open Label Day1 Treatment on 19FEB2021. Please review and reconcile.' answered with 'per source the OL-day1 was performed on 22 jan 2021' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:40:12
User opened query 'Per CDM, per sponsor review: Per IRT, Subject had Open Label Day1 Treatment on 19FEB2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 08:52:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '22 Jan 2021'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:33
	(b) (4)	

US3252399

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

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:08:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '08:03'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:33
	(b) (4)	

US3252399

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

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:08:40
User entered '22 Jan 2021 08:03'	System	23 Jan 2021 04:34:33

US3252399

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

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:08:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Left Arm (LEFT ARM)'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:33
	(b) (4)	

US3252399

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

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:08:40
User entered 'ONCE'	System	23 Jan 2021 04:34:33

US3252399

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

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:08:40
User entered 'INTRAMUSCULAR'	System	23 Jan 2021 04:34:33

US3252399

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:53
	(b) (4)	

US3252399

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '22 Jan 2021'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:53
	(b) (4)	

US3252399

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '07:45'	Shannon Moyer (b) (4)	23 Jan 2021 04:34:53
	(b) (4)	

US3252399

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '22 Jan 2021 07:45'	System	23 Jan 2021 04:34:53

US3252399

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:14:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	23 Jan 2021 04:35:02
	(b) (4)	

US3252399

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:14:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '22 Jan 2021'	Shannon Moyer (b) (4)	23 Jan 2021 04:35:02
	(b) (4)	

US3252399

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:14:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '07:45'	Shannon Moyer (b) (4)	23 Jan 2021 04:35:02
	(b) (4)	

US3252399

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '22 Jan 2021 07:45'	System	23 Jan 2021 04:35:02

US3252399

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

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	23 Jan 2021 04:35:05
	(b) (4)	

US3252399

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

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'I'	System	23 Jan 2021 04:35:05

US3252399

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:32
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Joanna Gurrola Mahoney	01 Feb 2021 05:22:03
	(b) (4)	

US3252399

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:32
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '29 Jan 2021'	Joanna Gurrola Mahoney	01 Feb 2021 05:22:03
	(b) (4)	

US3252399

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:32
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Contact Made (CONTACT MADE)'	Joanna Gurrola Mahoney	01 Feb 2021 05:22:03
	(b) (4)	

US3252399

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:32
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Joanna Gurrola Mahoney	01 Feb 2021 05:22:03
	(b) (4)	

US3252399

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:32
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Joanna Gurrola Mahoney	01 Feb 2021 05:22:09
	(b) (4)	

US3252399

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:32
User entered 'I'	System	01 Feb 2021 05:22:09

US3252399

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:32
User entered 'I'	System	01 Feb 2021 05:22:09
DataPoint set to visible.	System	01 Feb 2021 05:22:09

US3252399

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 03:57:55

US3252399

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '26 Feb 2021'	(b) (4), (b) (6)	01 Mar 2021 03:57:55

US3252399

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[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 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Mar 2021 03:57:55

US3252399

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'OLD29'	System	01 Mar 2021 03:57:55

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Mar 2021 03:58:42

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 03:58:42

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '26 Feb 2021'	(b) (4), (b) (6)	01 Mar 2021 03:58:42

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '09:54'	(b) (4), (b) (6)	01 Mar 2021 03:58:42

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '26 Feb 2021 09:54'	System	01 Mar 2021 03:58:42

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '98.2' F	(b) (4), (b) (6)	01 Mar 2021 03:58:42

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Mar 2021 03:58:42

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 03:58:42

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '99'	(b) (4), (b) (6)	01 Mar 2021 03:58:42

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'bpm'	System	01 Mar 2021 03:58:42

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '16'	(b) (4), (b) (6)	01 Mar 2021 03:58:42

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'breaths/min'	System	01 Mar 2021 03:58:42

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '103'	(b) (4), (b) (6)	01 Mar 2021 03:58:42

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'mmHg'	System	01 Mar 2021 03:58:42

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '72'	(b) (4), (b) (6)	01 Mar 2021 03:58:42

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'mmHg'	System	01 Mar 2021 03:58:42

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Mar 2021 03:59:25

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 03:59:25

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '26 Feb 2021'	(b) (4), (b) (6)	01 Mar 2021 03:59:25

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '10:55'	(b) (4), (b) (6)	01 Mar 2021 03:59:25

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '26 Feb 2021 10:55'	System	01 Mar 2021 03:59:25

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '97.7' F	(b) (4), (b) (6)	01 Mar 2021 03:59:25

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Mar 2021 03:59:25

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 03:59:25

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '76'	(b) (4), (b) (6)	01 Mar 2021 03:59:25

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'bpm'	System	01 Mar 2021 03:59:25

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '14'	(b) (4), (b) (6)	01 Mar 2021 03:59:25

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'breaths/min'	System	01 Mar 2021 03:59:25

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '118'	(b) (4), (b) (6)	01 Mar 2021 03:59:25

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'mmHg'	System	01 Mar 2021 03:59:25

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '79'	(b) (4), (b) (6)	01 Mar 2021 03:59:25

US3252399

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'mmHg'	System	01 Mar 2021 03:59:25

US3252399

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 03:59:33

US3252399

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 03:59:33

US3252399

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:26:13
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 03:59:59

US3252399

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:26:13
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 03:59:59

US3252399

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

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 Apr 2021 21:11:05
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:26:13
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 03:59:59

US3252399

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'mRNA-1273'	System	01 Mar 2021 03:59:59
DataPoint set to visible.	System	01 Feb 2021 05:22:09

US3252399

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:26:13
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '26 Feb 2021'	(b) (4), (b) (6)	01 Mar 2021 03:59:59

US3252399

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:26:13
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '10:19'	(b) (4), (b) (6)	01 Mar 2021 03:59:59

US3252399

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered '26 Feb 2021 10:19'	System	01 Mar 2021 03:59:59

US3252399

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:26:13
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	01 Mar 2021 03:59:59

US3252399

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:26:13
User entered 'ONCE'	System	01 Mar 2021 03:59:59

US3252399

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 03:59:59

US3252399

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 04:00:05

US3252399

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:11:05
User entered 'I'	System	01 Mar 2021 04:00:05

US3252399

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:12
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 02:43:33

US3252399

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:12
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered '6 Mar 2021'	(b) (4), (b) (6)	08 Mar 2021 02:43:33

US3252399

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:12
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Mar 2021 02:43:33

US3252399

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:12
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 02:43:33

US3252399

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:12
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 02:43:40

US3252399

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:12
User entered 'I'	System	08 Mar 2021 02:43:40

US3252399

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 02:29:44

US3252399

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered '26 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 02:29:44

US3252399

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	29 Mar 2021 02:29:44

US3252399

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:00

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User entered 'OLD57'	System	29 Mar 2021 02:29:44

US3252399

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 02:30:23

US3252399

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered '26 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 02:30:23

US3252399

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered '07:31'	(b) (4), (b) (6)	29 Mar 2021 02:30:23

US3252399

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User entered '26 Mar 2021 07:31'	System	29 Mar 2021 02:30:23

US3252399

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered '97.7' F	(b) (4), (b) (6)	29 Mar 2021 02:30:23

US3252399

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'Oral (Oral)'	(b) (4), (b) (6)	29 Mar 2021 02:30:23

US3252399

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 02:30:23

US3252399

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered '92'	(b) (4), (b) (6)	29 Mar 2021 02:30:23

US3252399

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User entered 'bpm'	System	29 Mar 2021 02:30:23

US3252399

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered '16'	(b) (4), (b) (6)	29 Mar 2021 02:30:23

US3252399

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User entered 'breaths/min'	System	29 Mar 2021 02:30:23

US3252399

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered '109'	(b) (4), (b) (6)	29 Mar 2021 02:30:23

US3252399

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User entered 'mmHg'	System	29 Mar 2021 02:30:23

US3252399

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered '76'	(b) (4), (b) (6)	29 Mar 2021 02:30:23

US3252399

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User entered 'mmHg'	System	29 Mar 2021 02:30:23

US3252399

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03

US3252399

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:00

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03

US3252399

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 02:30:31

US3252399

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:00

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 02:30:31

US3252399

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:52
User closed query 'Per GCL LAB Recon: Immunogenicity: GCL has an 26MAR2021 sample Barcode# 1F620986615 labelled as OL-D57. If Visit 4 DAY 209 and OL-D57 was performed on the same day then, Per CCG, OL-phase sample is collected but Immunogenicity form under both the visit is updated as yes. Since Visit 4Day209 and OL-D57 are overlapping visit then please update the Immunogenicity data under OL-D57 visit. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 14:39:23
Query 'Per GCL LAB Recon: Immunogenicity: GCL has an 26MAR2021 sample Barcode# 1F620986615 labelled as OL-D57. If Visit 4 DAY 209 and OL-D57 was performed on the same day then, Per CCG, OL-phase sample is collected but Immunogenicity form under both the visit is updated as yes. Since Visit 4Day209 and OL-D57 are overlapping visit then please update the Immunogenicity data under OL-D57 visit. Thank you. ' answered with 'updated as per query. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 06:15:32
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 06:15:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 06:15:07
User opened query 'Per GCL LAB Recon: Immunogenicity: GCL has an 26MAR2021 sample Barcode# 1F620986615 labelled as OL-D57. If Visit 4 DAY 209 and OL-D57 was performed on the same day then, Per CCG, OL-phase sample is collected but Immunogenicity form under both the visit is updated as yes. Since Visit 4Day209 and OL-D57 are overlapping visit then please update the Immunogenicity data under OL-D57 visit. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 08:15:39
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 02:30:43

US3252399

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:52
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 06:15:07
User entered '26 Mar 2021' reason for change: Data Entry Error		19 Apr 2021 06:15:07
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 02:30:43

US3252399

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:58:52
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 06:15:07
User entered '07:45' reason for change: Data Entry Error		19 Apr 2021 06:15:07
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 02:30:43

US3252399

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:03
User entered '26 Mar 2021 07:45'	System	19 Apr 2021 06:15:07
User entered empty.	System	29 Mar 2021 02:30:43

US3252399

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:14:00

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:40:45
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Signature has been broken.	(b) (4), (b) (6)	26 Mar 2021 15:06:17
User entered 'Yes (Y)' reason for change: New Information		26 Mar 2021 15:06:17
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:06:52
	(b) (4)	

US3252399

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:02
User entered	System	29 Mar 2021 15:46:46
'USA-US108-2021-mRNA-1273-P301000016'		
User entered 'New'	(b) (4), (b) (6)	29 Mar 2021 15:46:46

US3252399

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Cervix disorders (excl infections and inflammations), HLT: Cervix disorders NEC, PT: Cervical dysplasia, LLT: Cervical dysplasia - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 15:54:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 15:54:26
Data point term sent to Coder	System	26 Mar 2021 15:53:47
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 15:53:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 15:53:10
User entered 'Cervical dysplasia' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 15:53:10
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 15:08:17
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 15:08:17

US3252399

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 15:08:17

US3252399

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'No (N)'	(b) (4), (b) (6)	26 Mar 2021 15:08:17

US3252399

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'No (N)'	(b) (4), (b) (6)	26 Mar 2021 15:08:17

US3252399

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: The patient underwent planned trachelectomy on 08 Mar 2021. Please provide the start date when the event cervical dysplasia was first known/diagnosed.' answered with 'As per source same as initial. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 13:28:56
User opened query 'PV Query: The patient underwent planned trachelectomy on 08 Mar 2021. Please provide the start date when the event cervical dysplasia was first known/diagnosed.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 12:08:47
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User closed query 'PV Query: Please review event start date. Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 16:15:06
User closed query 'PV Query: Please provide the onset date for diagnosis of cervical dysplasia that required hospitalization for surgical treatment on 08Mar2021. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 16:10:57
Query 'PV Query: Please review event start date. Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. ' answered with 'as per patient event start date is same as start date' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 22:06:43
Query 'PV Query: Please provide the onset date for diagnosis of cervical dysplasia that required hospitalization for surgical treatment on 08Mar2021. ' answered with 'same as start date as per patient' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 22:04:55
User opened query 'PV Query: Please review event start date. Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 21:37:19

US3252399

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the onset date for diagnosis of cervical dysplasia that required hospitalization for surgical treatment on 08Mar2021. ' (Site from Safety). User entered '8 Mar 2021'	(b) (4), (b) (6)	20 Apr 2021 21:36:51
	(b) (4), (b) (6)	26 Mar 2021 15:08:17

US3252399

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
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	26 Mar 2021 21:39:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 21:39:17
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	26 Mar 2021 15:08:17
User entered '11:00'	(b) (4), (b) (6)	26 Mar 2021 15:08:17

US3252399

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 21:39:17
User entered '8 Mar 2021 11:00'	System	26 Mar 2021 15:08:17

US3252399

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'No (N)'	(b) (4), (b) (6)	26 Mar 2021 15:08:17

US3252399

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '9 Mar 2021'	(b) (4), (b) (6)	26 Mar 2021 15:08:17

US3252399

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
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	26 Mar 2021 21:39:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 21:39:17
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	26 Mar 2021 15:08:17
User entered '11:00'	(b) (4), (b) (6)	26 Mar 2021 15:08:17

US3252399

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 21:39:17
User entered '9 Mar 2021 11:00'	System	26 Mar 2021 15:08:17

US3252399

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 21:38:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 21:38:36
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 21:38:36
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 15:08:17
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 15:08:17

US3252399

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 21:38:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 21:38:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 21:38:36
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 15:55:24
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	26 Mar 2021 15:55:24
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 15:55:24
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 15:54:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 15:54:04
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	26 Mar 2021 15:54:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 15:54:04
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 15:08:17
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	26 Mar 2021 21:40:34
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	26 Mar 2021 21:40:34
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	26 Mar 2021 21:38:36
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 21:38:36
User entered '0'	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '8 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 21:38:36
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 13:22:06
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'It has been sent.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 03:37:57
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 19:26:49
User entered '9 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 21:38:36
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 21:40:34
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User closed query 'Participant was not hospitalized or System Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).		26 Mar 2021 21:44:06
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	26 Mar 2021 21:44:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 21:44:06
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	26 Mar 2021 21:40:34
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 21:40:34
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 21:38:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 21:38:36
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 21:38:36
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 15:08:17
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 21:38:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 21:38:36
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 21:38:36
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 15:08:17
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User closed query 'PV Query: As the last dose of study drug was given on 26 Feb2021, please update the action taken with study drug from " none" to "not applicable". ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 16:15:38
Query 'PV Query: As the last dose of study drug was given on 26 Feb2021, please update the action taken with study drug from " none" to "not applicable". ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 22:03:59
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 22:02:58
User opened query 'PV Query: As the last dose of study drug was given on 26 Feb2021, please update the action taken with study drug from " none" to "not applicable". ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 21:37:11
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 21:38:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 21:38:36
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 21:38:36
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 15:08:17
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

None

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure (#1) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:50:02
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure (#1) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 10:02:30
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 10:02:19
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure (#1) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 06:19:38
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	26 Mar 2021 21:38:36
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 21:38:36
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	26 Mar 2021 15:08:17
User entered '0'	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 10:02:19
User entered '0'	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 21:38:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 21:38:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 21:38:36
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 15:08:17
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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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)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User closed query 'PV Query: Please provide the reason for hysterectomy that was performed in 2013 per medical history. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 16:15:51
Query 'PV Query: Please provide the reason for hysterectomy that was performed in 2013 per medical history. ' answered with 'reason unknown' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 22:03:50
User opened query 'PV Query: Please provide the reason for hysterectomy that was performed in 2013 per medical history. ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 21:37:02
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. 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. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 13:24:50
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 13:23:37
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'The medical records has been sent.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 03:44:11
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. 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. If no results are available, please confirm in your response.' answered with 'it has been sent.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 03:39:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:00

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 16:13:38
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'The patient underwent surgery to have her cervix removed due to cervical dysplasia, the patient is stable and we are already requesting medical records.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 07:29:37
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 19:26:36
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. 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. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 19:26:28
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 19:26:19

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	29 Mar 2021 07:24:54
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	29 Mar 2021 07:24:54
User entered 'The patient underwent surgery to have her cervix removed due to cervical dysplasia, the patient is stable. trachelectomy was performed.' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 07:24:54
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Mar 2021 21:38:36
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Mar 2021 15:55:24
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	26 Mar 2021 15:55:24
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Mar 2021 15:54:04
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 15:08:17

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Folder: Adverse Events

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Mar 2021 15:54:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Mar 2021 15:08:17

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Mar 2021 21:40:34

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 04:55:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 04:55:01
Data point term sent to Coder	System	21 Apr 2021 04:54:31
User entered 'Headache'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '17 Oct 2020'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

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Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User closed query 'Start time is present for an AE thatSystem did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	21 Apr 2021 04:56:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 04:56:17
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	21 Apr 2021 04:54:09
User entered '16:54'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User entered empty.	System	21 Apr 2021 04:56:17
User entered '17 Oct 2020 16:54'	System	21 Apr 2021 04:54:09

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '22 Oct 2020'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:54:09

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User entered empty.	System	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'Related (RELATED)'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'None (NONE)'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '1'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User entered '0'	System	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03
User entered '0'	System	21 Apr 2021 04:54:09

US3252399

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:00

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 04:55:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	21 Apr 2021 04:55:51
User entered 'fatigue'	System (b) (4)	21 Apr 2021 04:55:31
	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '18 Oct 2020'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User closed query 'Start time is present for an AE thatSystem did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	21 Apr 2021 04:56:10
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 04:56:10
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	21 Apr 2021 04:55:05
User entered '12:16'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User entered empty.	System	21 Apr 2021 04:56:10
User entered '18 Oct 2020 12:16'	System	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '22 Oct 2020'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User entered empty.	System	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'Related (RELATED)'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'None (NONE)'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '1'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User entered '0'	System	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User entered '0'	System	21 Apr 2021 04:55:05

US3252399

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:00

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 04:56:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 04:56:54
Data point term sent to Coder	System	21 Apr 2021 04:56:32
User entered 'muscle aches'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '17 Oct 2020'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User closed query 'Start time is present for an AE thatSystem did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	21 Apr 2021 04:56:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 04:56:01
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	21 Apr 2021 04:55:53
User entered '16:54'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User entered empty.	System	21 Apr 2021 04:56:01
User entered '17 Oct 2020 16:54'	System	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '21 Oct 2020'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User entered empty.	System	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'Related (RELATED)'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'None (NONE)'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '1'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User entered '0'	System	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User entered '0'	System	21 Apr 2021 04:55:53

US3252399

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:00

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:14:00

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:40:45
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	02 Sep 2020 14:07:10
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:00

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Sep 2020 14:12:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Sep 2020 14:12:51
Data point term sent to Coder	System	02 Sep 2020 14:08:51
User entered 'vitamin c supplement'	Shannon Moyer (b) (4)	02 Sep 2020 14:07:56

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:07:56
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'general health'	Shannon Moyer (b) (4)	02 Sep 2020 14:07:56
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:00

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '1000'	Shannon Moyer (b) (4)	02 Sep 2020 14:07:56
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'mg (mg)'	Shannon Moyer (b) (4)	02 Sep 2020 14:07:56
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:07:56
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	02 Sep 2020 14:07:56
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:07:56
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:00

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	02 Sep 2020 14:07:56
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:07:56
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'UN Mar 2020'	Shannon Moyer (b) (4)	02 Sep 2020 14:07:56
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 14:07:56
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:00

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	02 Sep 2020 14:07:56
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:07:56
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:07:56
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 14:07:56

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 14:07:56

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 14:07:56

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:00

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 14:12:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 14:12:50
Data point term sent to Coder	System	02 Sep 2020 14:08:52
User entered 'zinc supplement'	Shannon Moyer (b) (4)	02 Sep 2020 14:08:46

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:08:46
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'GENERAL HEALTH'	Shannon Moyer (b) (4)	02 Sep 2020 14:08:46
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:00

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '15'	Shannon Moyer (b) (4)	02 Sep 2020 14:08:46
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'mg (mg)'	Shannon Moyer (b) (4)	02 Sep 2020 14:08:46
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:08:46
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	02 Sep 2020 14:08:46
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:08:46
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:00

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	02 Sep 2020 14:08:46
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:08:46
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'UN Mar 2020'	Shannon Moyer (b) (4)	02 Sep 2020 14:08:46
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 14:08:46
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:00

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	02 Sep 2020 14:08:46
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:08:46
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:08:46
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 14:08:46

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 14:08:46

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 14:08:46

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 14:12:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 14:12:54
Data point term sent to Coder	System	02 Sep 2020 14:09:53
User entered 'aspirin'	Shannon Moyer (b) (4)	02 Sep 2020 14:09:23

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	23 Sep 2020 23:38:24
User entered 'No (N)'	(b) (4)	
	Shannon Moyer (b) (4)	02 Sep 2020 14:09:23
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'general health'	Shannon Moyer (b) (4)	02 Sep 2020 14:09:23
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:00

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '81'	Shannon Moyer (b) (4)	02 Sep 2020 14:09:23
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'mg (mg)'	Shannon Moyer (b) (4)	02 Sep 2020 14:09:23
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:09:23
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	02 Sep 2020 14:09:23
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:09:23
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:00

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	02 Sep 2020 14:09:23
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:09:23
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:00

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'UN Mar 2020'	Shannon Moyer (b) (4)	02 Sep 2020 14:09:23
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered '0'	Shannon Moyer (b) (4)	02 Sep 2020 14:09:23
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:00

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	02 Sep 2020 14:09:23
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered empty.	Shannon Moyer (b) (4)	02 Sep 2020 14:09:23
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:09:23
	(b) (4)	

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 14:09:23

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 14:09:23

US3252399

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 14:09:23

US3252399

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:14:00

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:40:45
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Signature has been broken.	(b) (4), (b) (6)	26 Mar 2021 15:08:42
User entered 'Yes (Y)' reason for change: Data Entry Error		26 Mar 2021 15:08:42
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:38:02
User entered 'No (N)'	Shannon Moyer (b) (4)	02 Sep 2020 14:06:59
	(b) (4)	

US3252399

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:14:00

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	06 Apr 2021 22:27:04
User entered '08 Mar 2021'	(b) (4), (b) (6)	26 Mar 2021 15:51:05

US3252399

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:14:00

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the complete name of surgery performed. Update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 16:17:19
User signature succeeded.	Joel Solis (b) (4)	06 Apr 2021 22:27:04
Query 'Per DM CLR: Please update the indication to reflect the complete name of surgery performed. Update as appropriate, otherwise clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 10:06:58
User entered 'Trachelectomy surgery' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 10:06:47
User opened query 'Per DM CLR: Please update the indication to reflect the complete name of surgery performed. Update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 17:23:55
User entered 'surgery' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 15:51:55
User entered 'Cervical dysplasia'		26 Mar 2021 15:51:05

US3252399

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:14:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	06 Apr 2021 22:27:04
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	26 Mar 2021 15:51:05

US3252399

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:14:00

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	06 Apr 2021 22:27:04
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 15:51:05

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'USA-US108-2021-MRNA-1273-P301000016'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Yes (Y)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Yes (Y)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Joel'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Solis'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered '5201 N. 10th Street'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Mcallen'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'TX'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'carmpa'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'US'	System	29 Mar 2021 15:47:31

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 16:18:02
User entered '2'	System	07 Apr 2021 13:10:38
User entered '1'	System	29 Mar 2021 15:47:31

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'USA-US108-2021-MRNA-1273-P301000016'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Yes (Y)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Yes (Y)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Joel'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Solis'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered '5201 N. 10th Street'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Mcallen'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'TX'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'carmpa'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'US'	System	29 Mar 2021 15:47:31

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 16:18:02
User entered '2'	System	07 Apr 2021 13:10:38
User entered '1'	System	29 Mar 2021 15:47:31

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:14:00

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered '29/Mar/2021 11:47'	System	29 Mar 2021 15:47:31

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:14:00

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'I'	(b) (4), (b) (6)	29 Mar 2021 15:47:31

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'USA-US108-2021-MRNA-1273-P301000016'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Yes (Y)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Yes (Y)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Joel'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Solis'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered '5201 N. 10th Street'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Mcallen'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'TX'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'carmpa'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'US'	System	29 Mar 2021 15:47:31

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 16:18:02
User entered '2'	System	07 Apr 2021 13:10:38
User entered '1'	System	29 Mar 2021 15:47:31

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:14:00

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:27
User entered '07/Apr/2021 13:10'	System	07 Apr 2021 13:10:38

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:14:00

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	08 Apr 2021 02:05:27
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 13:10:38

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'USA-US108-2021-MRNA-1273-P301000016'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Yes (Y)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Yes (Y)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'No (N)'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Joel'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Solis'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered '5201 N. 10th Street'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'Mcallen'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'TX'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:47:16
User entered 'carmpa'	System	29 Mar 2021 15:46:46

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:11:43
User entered 'US'	System	29 Mar 2021 15:47:31

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 16:18:02
User entered '2'	System	07 Apr 2021 13:10:38
User entered '1'	System	29 Mar 2021 15:47:31

US3252399

Folder: SAE USA-US108-2021-MRNA-1273-P301000016

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:14:00

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:42:43
User entered '26/Apr/2021 09:17'	System	26 Apr 2021 16:18:02

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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)	28 Apr 2021 11:42:43
User entered 'I'	(b) (4), (b) (6)	26 Apr 2021 16:18:02