

US3252009 (Prod: Centex Studies Inc)

Generated By: KC Joubran

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US3252009

Form: Participant Creation

Data signed: (b) (4) 26 Feb 2021 22:26:56

Generated On: 11 Aug 2021 22:09:47

[Participant ID](#)

US3252009

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

US3252009

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3252009

Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Date of Birth (MMM yyyy)	(b) (6) 1987
Age	33
Age Units	YEARS
Age (Derived)	33
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	False
Black	False
Asian	True
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

US3252009

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Date of Informed Consent (*dd MMM yyyy*) 3 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

US3252009

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3252009

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Were any significant conditions reported?

Yes ☐

No ☒

US3252009

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	03 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:52 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 16:52
Height (<i>xxx.x</i>)	64.5 in
Weight (<i>xxx.x</i>)	162.6 lb
BMI (<i>xxx.x</i>)	27.53664 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)	

US3252009

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 22:27:00

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 AUG 2020

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

US3252009

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Date of assessment (*dd MMM yyyy*) 03 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (*dd MMM yyyy*) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____
Date of last menstruation unknown False

US3252009

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	03 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3252009

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 22:27:00

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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

US3252009

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

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)	False
Other	True
Specify	RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

US3252009

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 22:27:00

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Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3252009

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

What was the date of randomization? (dd MMM yyyy) 03 AUG 2020

What was the participant's randomization number? 142781

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 ☒

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Height	ND - Not Done
Weight	ND - Not Done

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

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)	03 AUG 2020
Time of assessment (00:00-23:59)	16:52 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 16:52
Temperature (xxx.x)	99.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

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)	03 AUG 2020
Time of assessment (00:00-23:59)	19:08 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 19:08
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3252009

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

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.

US3252009

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3252009

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

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) 3 AUG 2020

What was the treatment time? (00:00-23:59) 18:15 (24 HR)

Treatment Date and Time (derived) 3 AUG 2020 18:15

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

US3252009

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 22:27:00

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Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 AUG 2020
Collection time (00:00-23:59)	17:09 (24 HR)
Collection date and time (derived)	03 AUG 2020 17:09

US3252009

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Collection date (dd MMM yyyy)			03 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:08	03 AUG 2020 17:08
Nasopharyngeal Swab 2	No		

US3252009

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 18:51

PC Open Date & Time

03 AUG 2020 18:35

PC Close Date & Time

03 AUG 2020 21:05

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

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 98.7 °F

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

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

PC Time Stamp	04 AUG 2020 10:13
PC Open Date & Time	03 AUG 2020 22:00
PC Close Date & Time	04 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:47

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:47

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

98.5 °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

05 AUG 2020 18:50

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:47

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

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 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:47

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 19:16

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:47

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 ☒

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 09 AUG 2020 07:49

PC Open Date & Time 08 AUG 2020 12:00

PC Close Date & Time 09 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:47

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 ☒

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 09 AUG 2020 23:59

PC Open Date & Time 09 AUG 2020 12:00

PC Close Date & Time 10 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 18:52

PC Open Date & Time

03 AUG 2020 18:35

PC Close Date & Time

03 AUG 2020 21:05

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

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

04 AUG 2020 10:13

PC Open Date & Time

03 AUG 2020 22:00

PC Close Date & Time

04 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 18:51

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 19:17

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT	DAY 6
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	09 AUG 2020 07:49
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:47

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

09 AUG 2020 23:59

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

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 ☐

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 18:52
PC Open Date & Time	03 AUG 2020 18:35
PC Close Date & Time	03 AUG 2020 21:05

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

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 ☐

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 10:39
PC Open Date & Time	03 AUG 2020 22:00
PC Close Date & Time	04 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:47

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 ☐

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:47

Yes ☐

PC Time stamp

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:47

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 ☒

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:47

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 18:51
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:47

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 ☐

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:47

Yes ☐

PC Time stamp

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:47

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 ☒

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:47

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 19:17
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:47

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 ☒

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:47

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 07:50
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:47

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 ☒

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:47

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 23:59
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3252009

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3252009

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 22:26:59

Generated On: 11 Aug 2021 22:09:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3252009

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 22:26:59

Generated On: 11 Aug 2021 22:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252009

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 22:26:57

Generated On: 11 Aug 2021 22:09:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252009

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 22:26:57

Generated On: 11 Aug 2021 22:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252009

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 22:26:57

Generated On: 11 Aug 2021 22:09:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3252009

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 22:26:57

Generated On: 11 Aug 2021 22:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252009

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

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)	11 SEP 2020
Time of assessment (00:00-23:59)	07:43 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 07:43
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3252009

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

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.

US3252009

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3252009

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

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?

What was the treatment date? (dd MMM yyyy)

What was the treatment time? (00:00-23:59)

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3252009

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 SEP 2020
Collection time (00:00-23:59)	08:00 (24 HR)
Collection date and time (derived)	11 SEP 2020 08:00

US3252009

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:49	11 SEP 2020 07:49
Nasopharyngeal Swab 2	No		

US3252009

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252009

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 22:26:57

Generated On: 11 Aug 2021 22:09:47

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

US3252009

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 22:26:57

Generated On: 11 Aug 2021 22:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252009

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 22:26:59

Generated On: 11 Aug 2021 22:09:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252009

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 22:26:59

Generated On: 11 Aug 2021 22:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252009

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 22:26:59

Generated On: 11 Aug 2021 22:09:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252009

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 22:26:59

Generated On: 11 Aug 2021 22:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252009

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

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	VISIT3

US3252009

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

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) _____

US3252009

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

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.

US3252009

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

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)	07:24 (24 HR)
Collection date and time (derived)	28 SEP 2020 07:24

US3252009

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 OCT 2020 18:45:35
Patient Cloud Open Date & Time	03 OCT 2020 00:01
Patient Cloud Close Date & Time	07 OCT 2020 23:59

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

13 OCT 2020 08:58:19

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	19 OCT 2020 14:04:53
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 18:28:00
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 11:23:40
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

18 NOV 2020 12:17:25

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

02 DEC 2020 17:59:59

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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 DEC 2020 14:07:32

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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 <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"/>

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

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

Date and time of submission

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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 DEC 2020 18:36:27

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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 JAN 2021 20:39:35

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3252009

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:09:47

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

US3252009

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

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

US3252009

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 22:26:59

Generated On: 11 Aug 2021 22:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252009

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 22:26:57

Generated On: 11 Aug 2021 22:09:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252009

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 22:26:57

Generated On: 11 Aug 2021 22:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252009

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 22:26:57

Generated On: 11 Aug 2021 22:09:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252009

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 22:26:57

Generated On: 11 Aug 2021 22:09:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252009

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

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

US3252009

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3252009

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 18:43:13

Generated On: 11 Aug 2021 22:09:47

Date of updated informed consent (dd MMM yyyy)	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	True
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 checked="" type="radio"/> Amendment 6 or later <input type="radio"/>
Date of unblinding (dd MMM yyyy)	13 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 type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

US3252009

Folder: Unscheduled 01 Sep 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 26 Feb 2021 22:27:00

Generated On: 11 Aug 2021 22:09:47

Visit Date	1 SEP 2020
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	False
Pregnancy Test	True

US3252009

Folder: Unscheduled 01 Sep 2020

Form: Pregnancy Test

Data signed: (b) (4) 05 Apr 2021 19:37:05

Generated On: 11 Aug 2021 22:09:47

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	1 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input checked="" type="radio"/>
	Negative <input type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	1 SEP 2020
Collection time	12:18
Collection date and time (derived)	1 SEP 2020 12:18

US3252009

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Feb 2021 22:26:56

Generated On: 11 Aug 2021 22:09:47

Did the participant experience any adverse events?

Yes ☐

No ☒

If Yes, enter details on the Adverse Events form.

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Feb 2021 22:26:56

Generated On: 11 Aug 2021 22:09:47

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

Yes ☒

No ☐

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

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Feb 2021 22:26:56

Generated On: 11 Aug 2021 22:09:47

Name of Medication TRINESSA LO (0.18/0.25 MG)

Prophylaxis Yes ☒
No ☐

Indication CONTRACEPTIVE

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

115 of 941

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Feb 2021 22:26:56

Generated On: 11 Aug 2021 22:09:47

	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 APR 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"/>

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Feb 2021 22:26:56

Generated On: 11 Aug 2021 22:09:47

Name of Medication NATURE MADE PRENATAL
MULTIVITAMIN + 200MG DHA

Prophylaxis Yes ☒
No ☐

Indication PREGNANCY

Dose per administration 1

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

117 of 941

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Feb 2021 22:26:56

Generated On: 11 Aug 2021 22:09:47

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Feb 2021 22:26:56

Generated On: 11 Aug 2021 22:09:47

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU VACCINE

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify SHOT

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

119 of 941

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Feb 2021 22:26:56

Generated On: 11 Aug 2021 22:09:47

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3252009

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Feb 2021 22:26:56

Generated On: 11 Aug 2021 22:09:47

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3252009

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 26 Feb 2021 22:26:56

Generated On: 11 Aug 2021 22:09:47

Date of dosing discontinuation (dd MMM yyyy) 11 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input checked="" type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

US3252009

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 22 Apr 2021 18:43:13

Generated On: 11 Aug 2021 22:09:47

Date of study discontinuation/completion (dd MMM yyyy) 13 JAN 2021

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input checked="" type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

PATIENT REQUESTED TO BE UNBLINDED FROM STUDY DUE TO MOVING TO A DIFFERENT STATE, MINNESOTA. PATIENT STATES SHE CAN NO LONGER MAKE SITE VISITS.

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

Audit

US3252009 (Prod: Centex Studies Inc)

US3252009

Form: Participant Creation

Generated On: 11 Aug 2021 22:09:47

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'US3252009'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 21:49:14

US3252009

Form: Participant Creation

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:09:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	03 Aug 2020 23:35:05

US3252009

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '03 AUG 2020'	RWS_ENDPOINT	03 Aug 2020 21:49:15
	ENDPOINT (b) (4)	

US3252009

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Clinic (Clinic)'	Joanna Gurrola Mahoney (b) (4)	03 Aug 2020 23:35:05

US3252009

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:09:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'SCRN'	System	03 Aug 2020 23:35:05

US3252009

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:47

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered (b) (6) 1987'	RWS_ENDPOINT	03 Aug 2020 21:49:16
	ENDPOINT (b) (4)	

US3252009

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:47

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	05 Aug 2020 02:05:36
User entered '33' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	05 Aug 2020 02:05:36
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	05 Aug 2020 00:42:43
User entered '55'	Shannon Moyer (b) (4) (b) (4)	05 Aug 2020 00:42:43

US3252009

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:47

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'YEARS'	System	05 Aug 2020 00:42:43

US3252009

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:47

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered '33'	System	03 Aug 2020 23:35:15

US3252009

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:47

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Female (F)'	Shannon Moyer (b) (4)	05 Aug 2020 00:42:43
	(b) (4)	

US3252009

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:47

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Shannon Moyer (b) (4)	05 Aug 2020 00:42:43
	(b) (4)	

US3252009

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:47

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '0'	Shannon Moyer (b) (4)	05 Aug 2020 00:42:43
	(b) (4)	

US3252009

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:47

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '0'	Shannon Moyer (b) (4)	05 Aug 2020 00:42:43
	(b) (4)	

US3252009

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:47

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '1' reason for change: Data Entry Error	Xavier Morales (b) (4)	02 Sep 2020 12:37:19
User entered '0'	Shannon Moyer (b) (4)	05 Aug 2020 00:42:43

US3252009

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:47

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '0'	Shannon Moyer (b) (4)	05 Aug 2020 00:42:43
	(b) (4)	

US3252009

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:47

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '0'	Shannon Moyer (b) (4)	05 Aug 2020 00:42:43
	(b) (4)	

US3252009

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '0'	Shannon Moyer (b) (4)	05 Aug 2020 00:42:43
	(b) (4)	

US3252009

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:47

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 00:42:43
	(b) (4)	

US3252009

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:47

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '0'	Shannon Moyer (b) (4)	05 Aug 2020 00:42:43
	(b) (4)	

US3252009

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:47

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '0' reason for change: Data Entry Error	Xavier Morales (b) (4)	02 Sep 2020 12:37:19
User entered '1'	Shannon Moyer (b) (4)	05 Aug 2020 00:42:43

US3252009

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:47

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '3 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	03 Aug 2020 23:35:15

US3252009

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'Aug 2020'	System	03 Aug 2020 23:35:15

US3252009

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered '2020'	System	03 Aug 2020 23:35:15

US3252009

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:47

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 00:48:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 00:48:18
User entered 'Amendment 1 (1)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	05 Aug 2020 00:48:18
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 23:35:15
User entered empty.	Joanna Gurrola Mahoney (b) (4)	03 Aug 2020 23:35:15

US3252009

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	03 Aug 2020 23:35:15

US3252009

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	03 Aug 2020 23:35:15

US3252009

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:47

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	03 Aug 2020 23:35:15

US3252009

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:47

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 00:48:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 00:48:18
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	05 Aug 2020 00:48:18
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 23:35:15
User entered empty.	Joanna Gurrola Mahoney (b) (4)	03 Aug 2020 23:35:15

US3252009

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:47

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	RWS_ENDPOINT	03 Aug 2020 21:49:15
	ENDPOINT (b) (4)	

US3252009

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:47

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'I'	System	03 Aug 2020 23:35:19

US3252009

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	03 Aug 2020 23:35:19

US3252009

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:09:47

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	05 Aug 2020 02:11:46
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	05 Aug 2020 00:48:56

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	05 Aug 2020 02:14:12
	(b) (4)	

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '03 Aug 2020'	Shannon Moyer (b) (4)	05 Aug 2020 02:14:12
	(b) (4)	

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '16:52'	Shannon Moyer (b) (4)	05 Aug 2020 02:14:12
	(b) (4)	

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered '03 Aug 2020 16:52'	System	05 Aug 2020 02:14:12

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '64.5' in	Shannon Moyer (b) (4)	05 Aug 2020 02:14:12
DataPoint set to visible.	(b) (4) System	03 Aug 2020 23:35:19

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '162.6' lb	Shannon Moyer (b) (4)	05 Aug 2020 02:14:12
DataPoint set to visible.	(b) (4) System	03 Aug 2020 23:35:19

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
Amendment Manager: User entered '27.53664'	System	16 Sep 2020 23:41:52
User entered '27.5'	System	05 Aug 2020 02:14:12
DataPoint set to visible.	System	03 Aug 2020 23:35:19

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'kg/m2'	System	05 Aug 2020 02:14:12
DataPoint set to visible.	System	03 Aug 2020 23:35:19

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	19 Aug 2020 01:31:42
User entered '99.3' F	(b) (4)	
	Shannon Moyer (b) (4)	05 Aug 2020 02:14:12
	(b) (4)	

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 12:29:59
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Shannon Moyer (b) (4)	19 Aug 2020 01:31:49
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 01:31:42
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	19 Aug 2020 01:31:42
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	05 Aug 2020 02:14:12

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:14:12
	(b) (4)	

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	19 Aug 2020 01:31:42
User entered '81'	(b) (4)	
	Shannon Moyer (b) (4)	05 Aug 2020 02:14:12
	(b) (4)	

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'bpm'	System	05 Aug 2020 02:14:12

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	19 Aug 2020 01:31:42
User entered '16'	Shannon Moyer (b) (4)	05 Aug 2020 02:14:12

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'breaths/min'	System	05 Aug 2020 02:14:12

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	19 Aug 2020 01:31:42
User entered '102'	(b) (4)	
	Shannon Moyer (b) (4)	05 Aug 2020 02:14:12
	(b) (4)	

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'mmHg'	System	05 Aug 2020 02:14:12

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	19 Aug 2020 01:31:42
User entered '69'	(b) (4)	
	Shannon Moyer (b) (4)	05 Aug 2020 02:14:12
	(b) (4)	

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'mmHg'	System	05 Aug 2020 02:14:12

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48

US3252009

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48

US3252009

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	05 Aug 2020 02:14:48
	(b) (4)	

US3252009

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	23 Sep 2020 17:04:07
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		14 Sep 2020 22:32:54
User closed query 'The Physical Examination Date is System prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		14 Sep 2020 22:32:54
User entered '3 Aug 2020' reason for change: Data Entry Error	Uche Ehiemua (b) (4) (b) (4)	14 Sep 2020 22:32:54
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		14 Sep 2020 21:25:33
User closed query 'The Physical Examination Date is System prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		02 Sep 2020 19:00:06
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		02 Sep 2020 18:59:09
User entered '03 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	05 Aug 2020 02:14:48

US3252009

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:47

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '03 Aug 2020'	Shannon Moyer (b) (4)	05 Aug 2020 02:19:14
	(b) (4)	

US3252009

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:47

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	05 Aug 2020 02:19:14
	(b) (4)	

US3252009

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:19:14
	(b) (4)	

US3252009

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:19:14
	(b) (4)	

US3252009

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:19:14
	(b) (4)	

US3252009

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:47

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '0'	Shannon Moyer (b) (4)	05 Aug 2020 02:19:14
	(b) (4)	

US3252009

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:19:14
	(b) (4)	

US3252009

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:47

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '0'	Shannon Moyer (b) (4)	05 Aug 2020 02:19:14
	(b) (4)	

US3252009

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	05 Aug 2020 02:25:30
	(b) (4)	

US3252009

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '03 Aug 2020'	Shannon Moyer (b) (4)	05 Aug 2020 02:25:30
	(b) (4)	

US3252009

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Urine (URINE)'	Shannon Moyer (b) (4)	05 Aug 2020 02:25:30
	(b) (4)	

US3252009

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Negative (NEGATIVE)'	Shannon Moyer (b) (4)	05 Aug 2020 02:25:30
	(b) (4)	

US3252009

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:25:30
	(b) (4)	

US3252009

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:25:30
	(b) (4)	

US3252009

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:25:30
	(b) (4)	

US3252009

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered empty.	System	05 Aug 2020 02:25:30

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

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)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

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)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

[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)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

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)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

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)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

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)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

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)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

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)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User closed query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	System	05 Aug 2020 08:27:00
User entered '0' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 08:27:00
User opened query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	System	05 Aug 2020 02:27:35
User entered '1'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '0'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

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)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '0'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

[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)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '0'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

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)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '0'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '0'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'I'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Resident in a community with ongoing person to person transmission'	Shannon Moyer (b) (4)	05 Aug 2020 02:27:35
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:09:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	05 Aug 2020 02:29:37
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '03 Aug 2020'	Shannon Moyer (b) (4)	05 Aug 2020 02:29:37
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4)	05 Aug 2020 02:29:37
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:09:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'VISIT1'	System	05 Aug 2020 02:29:37

US3252009

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 22:09:16

US3252009

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:47

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:51:08
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:51:08
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Aug 2020 22:09:16
User entered '142781' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 22:09:16

US3252009

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 16:06:50
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'patient was stratified incorrectly, unable to correct ' (Site from System).	Xavier Morales (b) (4)	09 Oct 2020 13:11:57
Amendment Manager: User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	30 Sep 2020 21:10:54
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	30 Sep 2020 21:10:54
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	05 Aug 2020 02:30:22
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 22:09:16

US3252009

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:47

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)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:30:22
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:47

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)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:30:22
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:30:22
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:47

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:30:22
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:47

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:30:22
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 23:02:23
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	19 Aug 2020 01:32:59
User entered '64.5' in	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 23:02:23
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	19 Aug 2020 01:32:59
User entered '162.6' lb	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 23:02:23
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	19 Aug 2020 01:32:59
User entered '64.5' in	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 23:02:23
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	19 Aug 2020 01:32:59
User entered '162.6' lb	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '03 Aug 2020'	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '16:52'	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered '03 Aug 2020 16:52'	System	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '99.3' F	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '81'	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'bpm'	System	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '16'	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'breaths/min'	System	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '102'	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'mmHg'	System	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '69'	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'mmHg'	System	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 23:02:23
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	19 Aug 2020 01:32:59
User entered '64.5' in	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 23:02:23
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	19 Aug 2020 01:32:59
User entered '162.6' lb	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 20:26:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 20:26:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	17 Aug 2020 20:26:10
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 02:33:15
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '03 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4)	17 Aug 2020 20:26:10
User entered empty.	(b) (4)	
	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 12:27:07
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per Source, correct as is' (Site from System).	Shannon Moyer (b) (4)	19 Aug 2020 01:32:51
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	17 Aug 2020 20:26:10
User entered '19:08' reason for change: Data Entry Error	Shannon Moyer (b) (4)	17 Aug 2020 20:26:10
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered '03 Aug 2020 19:08'	System	17 Aug 2020 20:26:10
User entered empty.	System	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '98.4' F reason for change: Data Entry Error	Shannon Moyer (b) (4)	17 Aug 2020 20:26:10
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Oral (Oral)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	17 Aug 2020 20:26:10
User entered empty.	(b) (4)	
	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '59' reason for change: Data Entry	Shannon Moyer (b) (4)	17 Aug 2020 20:26:10
Error	(b) (4)	
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'bpm'	System	17 Aug 2020 20:26:10
User entered empty.	System	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '16' reason for change: Data Entry	Shannon Moyer (b) (4)	17 Aug 2020 20:26:10
Error	(b) (4)	
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'breaths/min'	System	17 Aug 2020 20:26:10
User entered empty.	System	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '133' reason for change: Data Entry	Shannon Moyer (b) (4)	17 Aug 2020 20:26:10
Error	(b) (4)	
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'mmHg'	System	17 Aug 2020 20:26:10
User entered empty.	System	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '75' reason for change: Data Entry	Shannon Moyer (b) (4)	17 Aug 2020 20:26:10
Error	(b) (4)	
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:33:15
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'mmHg'	System	17 Aug 2020 20:26:10
User entered empty.	System	05 Aug 2020 02:33:15

US3252009

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 23:03:46
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	05 Aug 2020 02:33:41

US3252009

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney	20 Aug 2020 23:03:46
User entered '03 Aug 2020'	(b) (4)	
	Shannon Moyer (b) (4)	05 Aug 2020 02:33:41
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User closed query 'Per CDM: Screening and dosing on the same day. Field should be marked No. Please review page and update accordingly with CCG's' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 07:54:23
Query 'Per CDM: Screening and dosing on the same day. Field should be marked No. Please review page and update accordingly with CCG's' answered with 'updated.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	14 Sep 2020 04:20:55
User closed query 'Was the pregnancy test performed is No, however data has been provided below. Please correct.' (Site from System).	System	14 Sep 2020 04:20:46
User opened query 'Was the pregnancy test performed is No, however data has been provided below. Please correct.' (Site from System).	System	14 Sep 2020 04:20:22
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Sep 2020 04:20:22
User opened query 'Per CDM: Screening and dosing on the same day. Field should be marked No. Please review page and update accordingly with CCG's' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 17:36:01
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	05 Aug 2020 02:34:18

US3252009

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Sep 2020 04:20:46
User entered '03 Aug 2020'	Shannon Moyer (b) (4)	05 Aug 2020 02:34:18

US3252009

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Sep 2020 04:20:46
User entered 'Urine (URINE)'	Shannon Moyer (b) (4)	05 Aug 2020 02:34:18

US3252009

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Sep 2020 04:20:46
User entered 'Negative (NEGATIVE)'	Shannon Moyer (b) (4)	05 Aug 2020 02:34:18

US3252009

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Sep 2020 04:20:46
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:34:18

US3252009

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:34:18
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:34:18
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered empty.	System	05 Aug 2020 02:34:18

US3252009

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 23:35:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 23:35:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Aug 2020 23:35:47
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 23:35:39
User entered empty.	Joanna Gurrola Mahoney (b) (4)	03 Aug 2020 23:35:39

US3252009

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	03 Aug 2020 23:35:39

US3252009

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

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)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	03 Aug 2020 23:35:39

US3252009

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'MRNA-1273 OR PLACEBO'	System	03 Aug 2020 23:35:47
User entered empty.	System	03 Aug 2020 23:35:39

US3252009

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '3 Aug 2020'	Joanna Gurrola Mahoney	03 Aug 2020 23:35:39
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '18:15'	Joanna Gurrola Mahoney (b) (4)	03 Aug 2020 23:35:39

US3252009

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered '3 Aug 2020 18:15'	System	03 Aug 2020 23:35:39

US3252009

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola Mahoney (b) (4)	03 Aug 2020 23:35:39

US3252009

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'ONCE'	System	03 Aug 2020 23:35:47
User entered empty.	System	03 Aug 2020 23:35:39

US3252009

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'INTRAMUSCULAR'	System	03 Aug 2020 23:35:47
User entered empty.	System	03 Aug 2020 23:35:39

US3252009

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	05 Aug 2020 02:34:50
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '03 Aug 2020'	Shannon Moyer (b) (4)	05 Aug 2020 02:34:50
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '17:09'	Shannon Moyer (b) (4)	05 Aug 2020 02:34:50
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered '03 Aug 2020 17:09'	System	05 Aug 2020 02:34:50

US3252009

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:09:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	05 Aug 2020 02:35:38
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	05 Aug 2020 02:35:38
User entered '03 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4)	05 Aug 2020 02:35:38
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	(b) (4)	
	System	05 Aug 2020 02:35:22
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:35:22
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	05 Aug 2020 02:35:22

US3252009

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	05 Aug 2020 02:35:22
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '17:08'	Shannon Moyer (b) (4)	05 Aug 2020 02:35:22
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered '03 Aug 2020 17:08'	System	05 Aug 2020 02:35:38
User entered empty.	System	05 Aug 2020 02:35:22

US3252009

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4) (b) (4)	05 Aug 2020 02:35:22

US3252009

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:35:22
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Shannon Moyer (b) (4)	05 Aug 2020 02:35:22
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered empty.	System	05 Aug 2020 02:35:22

US3252009

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	05 Aug 2020 02:35:51
	(b) (4)	

US3252009

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'I'	System	05 Aug 2020 02:35:51

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-03T18:51:27', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '0b9b4b2e-f9dc-4023-9559-705517a1989f' User entered 'Yes (Y)'	System	03 Aug 2020 23:51:49
	System	03 Aug 2020 23:51:49

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-03T18:51:31', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '0b9b4b2e-f9dc-4023-9559-705517a1989f' User entered '97.4'	System	03 Aug 2020 23:51:49
	System	03 Aug 2020 23:51:49

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-03T18:51:35', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '0b9b4b2e-f9dc-4023-9559-705517a1989f' User entered 'No (N)'	System	03 Aug 2020 23:51:49
	System	03 Aug 2020 23:51:49

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-03T18:51:47', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '0b9b4b2e-f9dc-4023-9559-705517a1989f' User entered '03 Aug 2020 18:51'	System	03 Aug 2020 23:51:49
	System	03 Aug 2020 23:51:49

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '03 Aug 2020 18:35'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '03 Aug 2020 21:05'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-04T10:13:08', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '73449d68-f392-4238-bb33-5de15bf47037' User entered 'Yes (Y)'	System	04 Aug 2020 15:13:25
	System	04 Aug 2020 15:13:25

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-04T10:13:13', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '73449d68-f392-4238-bb33-5de15bf47037' User entered '98.7'	System	04 Aug 2020 15:13:25
	System	04 Aug 2020 15:13:25

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-04T10:13:15', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '73449d68-f392-4238-bb33-5de15bf47037'	System	04 Aug 2020 15:13:25
User entered 'No (N)'	System	04 Aug 2020 15:13:25

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-04T10:13:20', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '73449d68-f392-4238-bb33-5de15bf47037' User entered '04 Aug 2020 10:13'	System	04 Aug 2020 15:13:25
	System	04 Aug 2020 15:13:25

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '03 Aug 2020 22:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 2'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:47

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 3'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-05T18:49:51', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '96017cf4-1cf2-4570-ab87-9ee7e7bc27e3'	System	05 Aug 2020 23:50:10
User entered 'Yes (Y)'	System	05 Aug 2020 23:50:10

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-05T18:49:55', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '96017cf4-1cf2-4570-ab87-9ee7e7bc27e3'	System	05 Aug 2020 23:50:10
User entered '98.5'	System	05 Aug 2020 23:50:10

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-05T18:49:57', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '96017cf4-1cf2-4570-ab87-9ee7e7bc27e3'	System	05 Aug 2020 23:50:10
User entered 'No (N)'	System	05 Aug 2020 23:50:10

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-05T18:50:08', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '96017cf4-1cf2-4570-ab87-9ee7e7bc27e3'	System	05 Aug 2020 23:50:10
User entered '05 Aug 2020 18:50'	System	05 Aug 2020 23:50:10

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 4'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:47

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 5'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-07T19:16:41', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '494ee8d7-fdec-482e-8c00-350d8164ed5c' User entered 'Yes (Y)'	System	08 Aug 2020 00:16:59
	System	08 Aug 2020 00:16:59

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-07T19:16:51', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '494ee8d7-fdec-482e-8c00-350d8164ed5c' User entered '97.8'	System	08 Aug 2020 00:16:59
	System	08 Aug 2020 00:16:59

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-07T19:16:53', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '494ee8d7-fdec-482e-8c00-350d8164ed5c'	System	08 Aug 2020 00:16:59
User entered 'No (N)'	System	08 Aug 2020 00:16:59

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-07T19:16:57', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '494ee8d7-fdec-482e-8c00-350d8164ed5c' User entered '07 Aug 2020 19:16'	System	08 Aug 2020 00:16:59
	System	08 Aug 2020 00:16:59

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 6'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T07:49:23', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '935111ce-1db2-4a4c-a7a1-eadb7885bc14' User entered 'No (N)'	System	09 Aug 2020 12:49:35
	System	09 Aug 2020 12:49:35

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T07:49:26', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '935111ce-1db2-4a4c-a7a1-eadb7885bc14' User entered 'No (N)'	System	09 Aug 2020 12:49:35
	System	09 Aug 2020 12:49:35

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T07:49:31', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '935111ce-1db2-4a4c-a7a1-eadb7885bc14' User entered '09 Aug 2020 07:49'	System	09 Aug 2020 12:49:35
	System	09 Aug 2020 12:49:35

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 7'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T23:59:22', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '25af6a34-a350-4563-bc1a-3cd5a35d15f1' User entered 'No (N)'	System	10 Aug 2020 04:59:29
	System	10 Aug 2020 04:59:29

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T23:59:24', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '25af6a34-a350-4563-bc1a-3cd5a35d15f1'	System	10 Aug 2020 04:59:29
User entered 'No (N)'	System	10 Aug 2020 04:59:29

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T23:59:27', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '25af6a34-a350-4563-bc1a-3cd5a35d15f1'	System	10 Aug 2020 04:59:29
User entered '09 Aug 2020 23:59'	System	10 Aug 2020 04:59:29

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-03T18:51:53', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '41a1725b-ed2-4a7d-a5bc-d5cbf4ab7749'	System	03 Aug 2020 23:52:17
User entered 'None (1)'	System	03 Aug 2020 23:52:17

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-03T18:52:04', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '41a1725b-ed2-4a7d-a5bc-d5cbf4ab7749' User entered 'No (N)'	System	03 Aug 2020 23:52:17
	System	03 Aug 2020 23:52:17

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-03T18:52:07', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '41a1725b-ed2-4a7d-a5bc-d5cbf4ab7749'	System	03 Aug 2020 23:52:17
User entered 'No (N)'	System	03 Aug 2020 23:52:17

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-03T18:52:10', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '41a1725b-ed2-4a7d-a5bc-d5cbf4ab7749'	System	03 Aug 2020 23:52:17
User entered 'None (1)'	System	03 Aug 2020 23:52:17

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-03T18:52:15', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '41a1725b-ed2-4a7d-a5bc-d5cbf4ab7749'	System	03 Aug 2020 23:52:17
User entered '03 Aug 2020 18:52'	System	03 Aug 2020 23:52:17

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '03 Aug 2020 18:35'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '03 Aug 2020 21:05'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-04T10:13:24', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'b3d5b5a9-a03b-4e67-977e-0f657db272f9'	System	04 Aug 2020 15:13:42
User entered 'None (1)'	System	04 Aug 2020 15:13:42

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-04T10:13:32', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'b3d5b5a9-a03b-4e67-977e-0f657db272f9'	System	04 Aug 2020 15:13:42
User entered 'No (N)'	System	04 Aug 2020 15:13:42

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-04T10:13:34', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'b3d5b5a9-a03b-4e67-977e-0f657db272f9'	System	04 Aug 2020 15:13:42
User entered 'No (N)'	System	04 Aug 2020 15:13:42

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-04T10:13:36', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'b3d5b5a9-a03b-4e67-977e-0f657db272f9'	System	04 Aug 2020 15:13:42
User entered 'None (1)'	System	04 Aug 2020 15:13:42

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-04T10:13:39', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'b3d5b5a9-a03b-4e67-977e-0f657db272f9'	System	04 Aug 2020 15:13:42
User entered '04 Aug 2020 10:13'	System	04 Aug 2020 15:13:42

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '03 Aug 2020 22:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 2'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 3'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-05T18:50:15', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'df9965e9-7cc4-4db5-9a79-f52f09d5cd15'	System	05 Aug 2020 23:51:13
User entered 'None (1)'	System	05 Aug 2020 23:51:13

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-05T18:50:20', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'df9965e9-7cc4-4db5-9a79-f52f09d5cd15'	System	05 Aug 2020 23:51:13
User entered 'No (N)'	System	05 Aug 2020 23:51:13

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-05T18:50:22', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'df9965e9-7cc4-4db5-9a79-f52f09d5cd15'	System	05 Aug 2020 23:51:13
User entered 'No (N)'	System	05 Aug 2020 23:51:13

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-05T18:50:25', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'df9965e9-7cc4-4db5-9a79-f52f09d5cd15'	System	05 Aug 2020 23:51:13
User entered 'None (1)'	System	05 Aug 2020 23:51:13

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-05T18:51:08', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'df9965e9-7cc4-4db5-9a79-f52f09d5cd15'	System	05 Aug 2020 23:51:13
User entered '05 Aug 2020 18:51'	System	05 Aug 2020 23:51:13

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 4'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 5'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-07T19:17:21', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'c06c94fe-11a9-46a2-a47c-f767488704b3'	System	08 Aug 2020 00:17:33
User entered 'None (1)'	System	08 Aug 2020 00:17:33

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-07T19:17:23', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'c06c94fe-11a9-46a2-a47c-f767488704b3'	System	08 Aug 2020 00:17:33
User entered 'No (N)'	System	08 Aug 2020 00:17:33

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-07T19:17:25', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'c06c94fe-11a9-46a2-a47c-f767488704b3'	System	08 Aug 2020 00:17:33
User entered 'No (N)'	System	08 Aug 2020 00:17:33

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-07T19:17:26', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'c06c94fe-11a9-46a2-a47c-f767488704b3'	System	08 Aug 2020 00:17:33
User entered 'None (1)'	System	08 Aug 2020 00:17:33

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-07T19:17:30', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'c06c94fe-11a9-46a2-a47c-f767488704b3' User entered '07 Aug 2020 19:17'	System	08 Aug 2020 00:17:33
	System	08 Aug 2020 00:17:33

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 6'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T07:49:36', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'b1b81a8b-c860-4cb3-ae1c-5a2290068687' User entered 'None (1)'	System	09 Aug 2020 12:49:51
	System	09 Aug 2020 12:49:51

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T07:49:39', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'b1b81a8b-c860-4cb3-ae1c-5a2290068687' User entered 'No (N)'	System	09 Aug 2020 12:49:51
	System	09 Aug 2020 12:49:51

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T07:49:42', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'b1b81a8b-c860-4cb3-ae1c-5a2290068687' User entered 'No (N)'	System	09 Aug 2020 12:49:51
	System	09 Aug 2020 12:49:51

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T07:49:44', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'b1b81a8b-c860-4cb3-ae1c-5a2290068687' User entered 'None (1)'	System	09 Aug 2020 12:49:51
	System	09 Aug 2020 12:49:51

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T07:49:48', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'b1b81a8b-c860-4cb3-ae1c-5a2290068687' User entered '09 Aug 2020 07:49'	System	09 Aug 2020 12:49:51
	System	09 Aug 2020 12:49:51

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 7'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T23:59:30', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'f83e4d5d-ffa0-4dae-badf-e37e443cc00d' User entered 'None (1)'	System	10 Aug 2020 04:59:42
	System	10 Aug 2020 04:59:42

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T23:59:32', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'f83e4d5d-ffa0-4dae-badf-e37e443cc00d' User entered 'No (N)'	System	10 Aug 2020 04:59:42
	System	10 Aug 2020 04:59:42

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T23:59:34', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'f83e4d5d-ffa0-4dae-badf-e37e443cc00d' User entered 'No (N)'	System	10 Aug 2020 04:59:42
	System	10 Aug 2020 04:59:42

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T23:59:36', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'f83e4d5d-ffa0-4dae-badf-e37e443cc00d' User entered 'None (1)'	System	10 Aug 2020 04:59:42
	System	10 Aug 2020 04:59:42

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T23:59:39', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'f83e4d5d-ffa0-4dae-badf-e37e443cc00d' User entered '09 Aug 2020 23:59'	System	10 Aug 2020 04:59:42
	System	10 Aug 2020 04:59:42

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-03T18:52:20', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '6b059216-1866-48d5-bab1-0d29e5a94ff2'	System	03 Aug 2020 23:52:44
User entered 'None (0)'	System	03 Aug 2020 23:52:44

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-03T18:52:22', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '6b059216-1866-48d5-bab1-0d29e5a94ff2' User entered 'None (0)'	System	03 Aug 2020 23:52:44
	System	03 Aug 2020 23:52:44

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-03T18:52:25', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '6b059216-1866-48d5-bab1-0d29e5a94ff2' User entered 'None (0)'	System	03 Aug 2020 23:52:44
	System	03 Aug 2020 23:52:44

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-03T18:52:27', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '6b059216-1866-48d5-bab1-0d29e5a94ff2' User entered 'None (0)'	System	03 Aug 2020 23:52:44
	System	03 Aug 2020 23:52:44

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-03T18:52:30', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '6b059216-1866-48d5-bab1-0d29e5a94ff2' User entered 'None (0)'	System	03 Aug 2020 23:52:44
	System	03 Aug 2020 23:52:44

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-03T18:52:33', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '6b059216-1866-48d5-bab1-0d29e5a94ff2'	System	03 Aug 2020 23:52:44
User entered 'None (0)'	System	03 Aug 2020 23:52:44

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-03T18:52:36', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '6b059216-1866-48d5-bab1-0d29e5a94ff2'	System	03 Aug 2020 23:52:44
User entered 'No (N)'	System	03 Aug 2020 23:52:44

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-03T18:52:42', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '6b059216-1866-48d5-bab1-0d29e5a94ff2' User entered '03 Aug 2020 18:52'	System	03 Aug 2020 23:52:44
	System	03 Aug 2020 23:52:44

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '03 Aug 2020 18:35'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '03 Aug 2020 21:05'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-04T10:39:42', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'f4448472-9b4e-4771-8346-2426797be552'	System	04 Aug 2020 15:40:03
User entered 'None (0)'	System	04 Aug 2020 15:40:03

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-04T10:39:44', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'f4448472-9b4e-4771-8346-2426797be552'	System	04 Aug 2020 15:40:03
User entered 'None (0)'	System	04 Aug 2020 15:40:03

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-04T10:39:46', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'f4448472-9b4e-4771-8346-2426797be552'	System	04 Aug 2020 15:40:03
User entered 'None (0)'	System	04 Aug 2020 15:40:03

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-04T10:39:47', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'f4448472-9b4e-4771-8346-2426797be552'	System	04 Aug 2020 15:40:03
User entered 'None (0)'	System	04 Aug 2020 15:40:03

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-04T10:39:48', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'f4448472-9b4e-4771-8346-2426797be552'	System	04 Aug 2020 15:40:03
User entered 'None (0)'	System	04 Aug 2020 15:40:03

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-04T10:39:50', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'f4448472-9b4e-4771-8346-2426797be552'	System	04 Aug 2020 15:40:03
User entered 'None (0)'	System	04 Aug 2020 15:40:03

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-04T10:39:54', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'f4448472-9b4e-4771-8346-2426797be552'	System	04 Aug 2020 15:40:03
User entered 'No (N)'	System	04 Aug 2020 15:40:03

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-04T10:39:59', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'f4448472-9b4e-4771-8346-2426797be552'	System	04 Aug 2020 15:40:03
User entered '04 Aug 2020 10:39'	System	04 Aug 2020 15:40:03

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '03 Aug 2020 22:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 2'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 3'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-05T18:51:12', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '57fe3c2e-5101-4612-9ae6-1463f54ac554' User entered 'None (0)'	System	05 Aug 2020 23:51:46
	System	05 Aug 2020 23:51:46

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-05T18:51:14', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '57fe3c2e-5101-4612-9ae6-1463f54ac554' User entered 'None (0)'	System	05 Aug 2020 23:51:46
	System	05 Aug 2020 23:51:46

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-05T18:51:17', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '57fe3c2e-5101-4612-9ae6-1463f54ac554' User entered 'None (0)'	System	05 Aug 2020 23:51:46
	System	05 Aug 2020 23:51:46

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-05T18:51:19', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '57fe3c2e-5101-4612-9ae6-1463f54ac554' User entered 'None (0)'	System	05 Aug 2020 23:51:46
	System	05 Aug 2020 23:51:46

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-05T18:51:20', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '57fe3c2e-5101-4612-9ae6-1463f54ac554' User entered 'None (0)'	System	05 Aug 2020 23:51:46
	System	05 Aug 2020 23:51:46

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-05T18:51:32', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '57fe3c2e-5101-4612-9ae6-1463f54ac554' User entered 'None (0)'	System	05 Aug 2020 23:51:46
	System	05 Aug 2020 23:51:46

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-05T18:51:37', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '57fe3c2e-5101-4612-9ae6-1463f54ac554'	System	05 Aug 2020 23:51:46
User entered 'No (N)'	System	05 Aug 2020 23:51:46

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-05T18:51:45', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '57fe3c2e-5101-4612-9ae6-1463f54ac554' User entered '05 Aug 2020 18:51'	System	05 Aug 2020 23:51:46
	System	05 Aug 2020 23:51:46

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 4'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 5'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-07T19:17:02', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'b02ae4ab-b6c2-4719-a9b1-9d007de02b3c' User entered 'None (0)'	System	08 Aug 2020 00:17:21
	System	08 Aug 2020 00:17:21

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-07T19:17:05', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'b02ae4ab-b6c2-4719-a9b1-9d007de02b3c' User entered 'None (0)'	System	08 Aug 2020 00:17:21
	System	08 Aug 2020 00:17:21

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-07T19:17:07', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'b02ae4ab-b6c2-4719-a9b1-9d007de02b3c' User entered 'None (0)'	System	08 Aug 2020 00:17:21
	System	08 Aug 2020 00:17:21

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-07T19:17:08', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'b02ae4ab-b6c2-4719-a9b1-9d007de02b3c' User entered 'None (0)'	System	08 Aug 2020 00:17:21
	System	08 Aug 2020 00:17:21

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-07T19:17:09', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'b02ae4ab-b6c2-4719-a9b1-9d007de02b3c' User entered 'None (0)'	System	08 Aug 2020 00:17:21
	System	08 Aug 2020 00:17:21

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-07T19:17:11', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'b02ae4ab-b6c2-4719-a9b1-9d007de02b3c' User entered 'None (0)'	System	08 Aug 2020 00:17:21
	System	08 Aug 2020 00:17:21

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-07T19:17:14', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'b02ae4ab-b6c2-4719-a9b1-9d007de02b3c' User entered 'No (N)'	System	08 Aug 2020 00:17:21
	System	08 Aug 2020 00:17:21

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-07T19:17:18', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'b02ae4ab-b6c2-4719-a9b1-9d007de02b3c' User entered '07 Aug 2020 19:17'	System	08 Aug 2020 00:17:21
	System	08 Aug 2020 00:17:21

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 6'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T07:49:53', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '01f598e9-1ba6-4c4b-b4dc-03e7b4b4a6c8' User entered 'None (0)'	System	09 Aug 2020 12:50:23
	System	09 Aug 2020 12:50:23

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T07:49:55', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '01f598e9-1ba6-4c4b-b4dc-03e7b4b4a6c8' User entered 'None (0)'	System	09 Aug 2020 12:50:23
	System	09 Aug 2020 12:50:23

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T07:49:58', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '01f598e9-1ba6-4c4b-b4dc-03e7b4b4a6c8' User entered 'None (0)'	System	09 Aug 2020 12:50:23
	System	09 Aug 2020 12:50:23

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T07:50:08', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '01f598e9-1ba6-4c4b-b4dc-03e7b4b4a6c8'	System	09 Aug 2020 12:50:23
User entered 'No interference with activity (1)'	System	09 Aug 2020 12:50:23

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T07:50:11', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '01f598e9-1ba6-4c4b-b4dc-03e7b4b4a6c8' User entered 'None (0)'	System	09 Aug 2020 12:50:23
	System	09 Aug 2020 12:50:23

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T07:50:12', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '01f598e9-1ba6-4c4b-b4dc-03e7b4b4a6c8' User entered 'None (0)'	System	09 Aug 2020 12:50:23
	System	09 Aug 2020 12:50:23

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T07:50:14', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '01f598e9-1ba6-4c4b-b4dc-03e7b4b4a6c8' User entered 'No (N)'	System	09 Aug 2020 12:50:23
	System	09 Aug 2020 12:50:23

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T07:50:21', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '01f598e9-1ba6-4c4b-b4dc-03e7b4b4a6c8' User entered '09 Aug 2020 07:50'	System	09 Aug 2020 12:50:23
	System	09 Aug 2020 12:50:23

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 7'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T23:59:42', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '10ac5c47-34e9-4012-ab93-327446dc21ff' User entered 'None (0)'	System	10 Aug 2020 04:59:57
	System	10 Aug 2020 04:59:57

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T23:59:44', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '10ac5c47-34e9-4012-ab93-327446dc21ff' User entered 'None (0)'	System	10 Aug 2020 04:59:57
	System	10 Aug 2020 04:59:57

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T23:59:46', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '10ac5c47-34e9-4012-ab93-327446dc21ff' User entered 'None (0)'	System	10 Aug 2020 04:59:57
	System	10 Aug 2020 04:59:57

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T23:59:47', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '10ac5c47-34e9-4012-ab93-327446dc21ff' User entered 'None (0)'	System	10 Aug 2020 04:59:57
	System	10 Aug 2020 04:59:57

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T23:59:48', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '10ac5c47-34e9-4012-ab93-327446dc21ff' User entered 'None (0)'	System	10 Aug 2020 04:59:57
	System	10 Aug 2020 04:59:57

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T23:59:50', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '10ac5c47-34e9-4012-ab93-327446dc21ff' User entered 'None (0)'	System	10 Aug 2020 04:59:57
	System	10 Aug 2020 04:59:57

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T23:59:52', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '10ac5c47-34e9-4012-ab93-327446dc21ff' User entered 'No (N)'	System	10 Aug 2020 04:59:57
	System	10 Aug 2020 04:59:57

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0694E933-1143-4915-93AC-BA6F7C0AEFDB)', Time: '2020-08-09T23:59:55', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '10ac5c47-34e9-4012-ab93-327446dc21ff' User entered '09 Aug 2020 23:59'	System	10 Aug 2020 04:59:57
	System	10 Aug 2020 04:59:57

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	09 Aug 2020 12:50:23
User entered 'Day 8'	System	09 Aug 2020 12:50:23

US3252009

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:09:47

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 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:09:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09

US3252009

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:09:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '10 Aug 2020 12:00'	System	09 Aug 2020 12:50:23

US3252009

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:09:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
User entered '11 Aug 2020 11:59'	System	09 Aug 2020 12:50:23

US3252009

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	13 Aug 2020 22:01:44
	(b) (4)	

US3252009

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '13 Aug 2020'	Shannon Moyer (b) (4)	13 Aug 2020 22:01:44
	(b) (4)	

US3252009

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	13 Aug 2020 22:01:44
	(b) (4)	

US3252009

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Shannon Moyer (b) (4)	13 Aug 2020 22:01:44
	(b) (4)	

US3252009

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	13 Aug 2020 22:01:27
	(b) (4)	

US3252009

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'I'	System	13 Aug 2020 22:01:27

US3252009

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	19 Aug 2020 23:18:16
	(b) (4)	

US3252009

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered '19 Aug 2020'	Shannon Moyer (b) (4)	19 Aug 2020 23:18:16
	(b) (4)	

US3252009

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	19 Aug 2020 23:18:16
	(b) (4)	

US3252009

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Shannon Moyer (b) (4)	19 Aug 2020 23:18:16
	(b) (4)	

US3252009

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	19 Aug 2020 23:18:21
	(b) (4)	

US3252009

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'I'	System	19 Aug 2020 23:18:21

US3252009

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	26 Aug 2020 03:31:30
	(b) (4)	

US3252009

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered '24 Aug 2020'	Shannon Moyer (b) (4)	26 Aug 2020 03:31:30
	(b) (4)	

US3252009

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	26 Aug 2020 03:31:30
	(b) (4)	

US3252009

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Shannon Moyer (b) (4)	26 Aug 2020 03:31:30
	(b) (4)	

US3252009

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	26 Aug 2020 03:31:11
	(b) (4)	

US3252009

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:48
User entered 'I'	System	26 Aug 2020 03:31:11

US3252009

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 21:25:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 21:25:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	14 Sep 2020 21:25:33
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 19:00:06
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 19:00:06
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 18:59:09

US3252009

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 21:50:53
Amendment Manager: Query text changed to "Visit 2 System Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates."		16 Sep 2020 23:41:51
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Correct as is per source' (Site from System).	Xavier Morales (b) (4)	14 Sep 2020 21:27:19
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	14 Sep 2020 21:25:33
User entered '11 Sep 2020' reason for change: Data Entry Error	Xavier Morales (b) (4)	14 Sep 2020 21:25:33
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	02 Sep 2020 19:00:06
User entered '01 Sep 2020'	Shannon Moyer (b) (4)	02 Sep 2020 18:59:09

US3252009

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Clinic (Clinic)' reason for change:	Xavier Morales (b) (4)	14 Sep 2020 21:25:33
Data Entry Error	(b) (4)	
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	02 Sep 2020 19:00:06
User entered 'Clinic (Clinic)'	(b) (4)	
	Shannon Moyer (b) (4)	02 Sep 2020 18:59:09
	(b) (4)	

US3252009

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered 'VISIT2'	System	14 Sep 2020 21:25:33
User entered empty.	System	02 Sep 2020 19:00:06
User entered 'VISIT2'	System	02 Sep 2020 18:59:09

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User accepted default value 'Pre-Dose (PREDOSE)'	Joanna Gurrola Mahoney	11 Sep 2020 22:04:39
	(b) (4)	

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '11 Sep 2020'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '07:43'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered '11 Sep 2020 07:43'	System	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '98.5' F	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Oral (Oral)'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '73'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered 'bpm'	System	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '15'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered 'breaths/min'	System	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Sep 2020 22:05:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Sep 2020 22:05:01
User entered '107' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:05:01
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Sep 2020 22:04:39
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered 'mmHg'	System	11 Sep 2020 22:05:01
User entered empty.	System	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Sep 2020 22:05:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Sep 2020 22:05:01
User entered '68' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:05:01
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Sep 2020 22:04:39
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered 'mmHg'	System	11 Sep 2020 22:05:01
User entered empty.	System	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User accepted default value 'Post-Dose (POSTDOSE)'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 22:05:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 22:05:19
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:05:19
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 22:04:39
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered empty.	System	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered empty.	System	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered empty.	System	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered empty.	System	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered empty.	System	11 Sep 2020 22:04:39

US3252009

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:05:53

US3252009

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:05:53

US3252009

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:06:12

US3252009

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:06:12

US3252009

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:06:12

US3252009

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:06:12

US3252009

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:06:12

US3252009

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:06:12

US3252009

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:06:12

US3252009

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered empty.	System	11 Sep 2020 22:06:12

US3252009

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:06:30

US3252009

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Pregnancy (PREGNANCY)'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:06:30

US3252009

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

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)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:06:30

US3252009

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered empty.	System	11 Sep 2020 22:06:30

US3252009

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:06:30

US3252009

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:06:30

US3252009

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered empty.	System	11 Sep 2020 22:06:30

US3252009

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:06:30

US3252009

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered empty.	System	11 Sep 2020 22:06:30

US3252009

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered empty.	System	11 Sep 2020 22:06:30

US3252009

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:07:08

US3252009

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '11 Sep 2020'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:07:08

US3252009

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '08:00'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:07:08

US3252009

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered '11 Sep 2020 08:00'	System	11 Sep 2020 22:07:08

US3252009

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:09:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '11 Sep 2020'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:08:16

US3252009

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:08:16

US3252009

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:08:16

US3252009

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '07:49'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:08:16

US3252009

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered '11 Sep 2020 07:49'	System	11 Sep 2020 22:08:16

US3252009

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:08:16

US3252009

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:08:16

US3252009

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:08:16

US3252009

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered empty.	System	11 Sep 2020 22:08:16

US3252009

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	11 Sep 2020 22:08:24

US3252009

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered '1'	System	11 Sep 2020 22:08:24

US3252009

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'No (N)'	Shannon Moyer (b) (4)	12 Sep 2020 20:25:18
	(b) (4)	

US3252009

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Shannon Moyer (b) (4)	12 Sep 2020 20:25:18
	(b) (4)	

US3252009

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Shannon Moyer (b) (4)	12 Sep 2020 20:25:18
	(b) (4)	

US3252009

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Shannon Moyer (b) (4)	12 Sep 2020 20:25:18
	(b) (4)	

US3252009

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	12 Sep 2020 20:25:24
	(b) (4)	

US3252009

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered 'I'	System	12 Sep 2020 20:25:24

US3252009

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Uche Ehiemua (b) (4)	16 Sep 2020 14:16:47
	(b) (4)	

US3252009

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '16 Sep 2020' reason for change: Data Entry Error	Uche Ehiemua (b) (4)	16 Sep 2020 14:18:32
User entered '15 Sep 2020'	Uche Ehiemua (b) (4)	16 Sep 2020 14:16:47

US3252009

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Contact Made (CONTACT MADE)'	Uche Ehiemua (b) (4)	16 Sep 2020 14:16:47

US3252009

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Uche Ehiemua (b) (4)	16 Sep 2020 14:16:47
	(b) (4)	

US3252009

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Uche Ehiemua (b) (4)	16 Sep 2020 14:17:12
	(b) (4)	

US3252009

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered 'I'	System	16 Sep 2020 14:17:12

US3252009

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	26 Sep 2020 07:24:55
	(b) (4)	

US3252009

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '25 Sep 2020'	Nancy Torrence (b) (4)	26 Sep 2020 07:24:55
	(b) (4)	

US3252009

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	26 Sep 2020 07:24:55
	(b) (4)	

US3252009

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Nancy Torrence (b) (4)	26 Sep 2020 07:24:55
	(b) (4)	

US3252009

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	26 Sep 2020 07:25:00
	(b) (4)	

US3252009

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered 'I'	System	26 Sep 2020 07:25:00

US3252009

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 15:58:54

US3252009

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '28 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 15:58:54

US3252009

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	29 Sep 2020 15:58:54

US3252009

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered 'VISIT3'	System	29 Sep 2020 15:58:54

US3252009

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User closed query 'Per CDM: As Per CCG, Vital signs page need to be filled, Please update else clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:07:57
Query 'Per CDM: As Per CCG, Vital signs page need to be filled, Please update else clarify. ' answered with 'Vital signs were not taken, deviation has been recorded.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	23 Oct 2020 16:52:57
User opened query 'Per CDM: As Per CCG, Vital signs page need to be filled, Please update else clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 16:52:30
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 15:59:09

US3252009

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 15:59:09

US3252009

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 15:59:09

US3252009

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered empty.	System	29 Sep 2020 15:59:09

US3252009

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 15:59:09

US3252009

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 15:59:09

US3252009

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 15:59:09

US3252009

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 15:59:09

US3252009

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered empty.	System	29 Sep 2020 15:59:09

US3252009

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 15:59:09

US3252009

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered empty.	System	29 Sep 2020 15:59:09

US3252009

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 15:59:09

US3252009

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered empty.	System	29 Sep 2020 15:59:09

US3252009

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 15:59:09

US3252009

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered empty.	System	29 Sep 2020 15:59:09

US3252009

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45

US3252009

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45

US3252009

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 15:59:16

US3252009

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 15:59:16

US3252009

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 15:59:35

US3252009

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '28 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 15:59:35

US3252009

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '07:24'	(b) (4), (b) (6)	29 Sep 2020 15:59:35

US3252009

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered '28 Sep 2020 07:24'	System	29 Sep 2020 15:59:35

US3252009

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 15:59:44

US3252009

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered '1'	System	29 Sep 2020 15:59:44

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 64'	System	03 Aug 2020 23:35:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-10-07T18:45:22', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'dd7f9325-7a25-456c-a9cd-09a2a97c93d7'	System	07 Oct 2020 23:45:39
User entered 'No (N)'	System	07 Oct 2020 23:45:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

Have you been exposed to someone with 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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-10-07T18:45:29', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'dd7f9325-7a25-456c-a9cd-09a2a97c93d7'	System	07 Oct 2020 23:45:39
User entered 'No (N)'	System	07 Oct 2020 23:45:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-10-07T18:45:35', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'dd7f9325-7a25-456c-a9cd-09a2a97c93d7' User entered '07 Oct 2020 18:45:35'	System	07 Oct 2020 23:45:39
	System	07 Oct 2020 23:45:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered '03 Oct 2020 00:01'	System	03 Aug 2020 23:35:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered '07 Oct 2020 23:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 71'	System	03 Aug 2020 23:35:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-10-13T08:58:08', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '8125f2ae-dede-4918-85e3-7a63201f2468'	System	13 Oct 2020 13:58:39
User entered 'No (N)'	System	13 Oct 2020 13:58:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

Have you been exposed to someone with 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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-10-13T08:58:03', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '8125f2ae-dede-4918-85e3-7a63201f2468'	System	13 Oct 2020 13:58:39
User entered 'No (N)'	System	13 Oct 2020 13:58:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-10-13T08:58:19', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '8125f2ae-dede-4918-85e3-7a63201f2468' User entered '13 Oct 2020 08:58:19'	System	13 Oct 2020 13:58:39
	System	13 Oct 2020 13:58:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered '10 Oct 2020 00:01'	System	03 Aug 2020 23:35:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered '14 Oct 2020 23:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 78'	System	03 Aug 2020 23:35:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-10-19T14:04:19', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'cb7d74c4-8720-442c-bef7-c6409e1e4b6e'	System	19 Oct 2020 19:04:55
User entered 'Yes (Y)'	System	19 Oct 2020 19:04:55

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

Have you been exposed to someone with 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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-10-19T14:04:22', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'cb7d74c4-8720-442c-bef7-c6409e1e4b6e'	System	19 Oct 2020 19:04:55
User entered 'No (N)'	System	19 Oct 2020 19:04:55

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-10-19T14:04:30', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'cb7d74c4-8720-442c-bef7-c6409e1e4b6e'	System	19 Oct 2020 19:04:55
User entered 'No (N)'	System	19 Oct 2020 19:04:55

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-10-19T14:04:35', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'cb7d74c4-8720-442c-bef7-c6409e1e4b6e'	System	19 Oct 2020 19:04:55
User entered 'No (N)'	System	19 Oct 2020 19:04:55

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-10-19T14:04:53', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'cb7d74c4-8720-442c-bef7-c6409e1e4b6e' User entered '19 Oct 2020 14:04:53'	System	19 Oct 2020 19:04:55
	System	19 Oct 2020 19:04:55

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered '17 Oct 2020 00:01'	System	03 Aug 2020 23:35:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered '21 Oct 2020 23:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 92'	System	03 Aug 2020 23:35:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-11-03T18:27:55', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '68b7b4f2-dcf8-4b5b-b547-8a36f7af2b6f' User entered 'No (N)'	System	04 Nov 2020 00:28:04
	System	04 Nov 2020 00:28:04

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Have you been exposed to someone with 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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-11-03T18:27:57', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '68b7b4f2-dcf8-4b5b-b547-8a36f7af2b6f' User entered 'No (N)'	System	04 Nov 2020 00:28:04
	System	04 Nov 2020 00:28:04

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-11-03T18:28:00', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '68b7b4f2-dcf8-4b5b-b547-8a36f7af2b6f' User entered '03 Nov 2020 18:28:00'	System	04 Nov 2020 00:28:04
	System	04 Nov 2020 00:28:04

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered '31 Oct 2020 00:01'	System	03 Aug 2020 23:35:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered '04 Nov 2020 23:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 99'	System	03 Aug 2020 23:35:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-11-09T11:23:25', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '74bf0907-83a7-41b4-b151-da64854e0f94'	System	09 Nov 2020 17:23:43
User entered 'No (N)'	System	09 Nov 2020 17:23:43

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

Have you been exposed to someone with 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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-11-09T11:23:33', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '74bf0907-83a7-41b4-b151-da64854e0f94'	System	09 Nov 2020 17:23:43
User entered 'No (N)'	System	09 Nov 2020 17:23:43

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-11-09T11:23:40', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '74bf0907-83a7-41b4-b151-da64854e0f94'	System	09 Nov 2020 17:23:43
User entered '09 Nov 2020 11:23:40'	System	09 Nov 2020 17:23:43

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered '07 Nov 2020 00:01'	System	03 Aug 2020 23:35:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered '11 Nov 2020 23:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered 'Day 106'	System	03 Aug 2020 23:35:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-11-18T12:17:20', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'be6f55e0-51a9-4c19-91cc-e92bd2ba687e' User entered 'No (N)'	System	18 Nov 2020 18:17:27
	System	18 Nov 2020 18:17:27

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

Have you been exposed to someone with 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 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-11-18T12:17:22', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'be6f55e0-51a9-4c19-91cc-e92bd2ba687e' User entered 'No (N)'	System	18 Nov 2020 18:17:27
	System	18 Nov 2020 18:17:27

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-11-18T12:17:25', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: 'be6f55e0-51a9-4c19-91cc-e92bd2ba687e' User entered '18 Nov 2020 12:17:25'	System	18 Nov 2020 18:17:27
	System	18 Nov 2020 18:17:27

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered '14 Nov 2020 00:01'	System	03 Aug 2020 23:35:39

US3252009

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:09
Data entry locked.	System	03 Aug 2020 23:35:39
User entered '18 Nov 2020 23:59'	System	03 Aug 2020 23:35:39

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[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)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

Have you been exposed to someone with 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)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[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)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

Have you been exposed to someone with 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)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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)	02 May 2021 13:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-12-02T17:59:54', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '93845536-aa9b-425f-a25f-754335ed7b39'	System	03 Dec 2020 00:00:05
User entered 'No (N)'	System	03 Dec 2020 00:00:05

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

Have you been exposed to someone with 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)	02 May 2021 13:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-12-02T17:59:56', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '93845536-aa9b-425f-a25f-754335ed7b39'	System	03 Dec 2020 00:00:05
User entered 'No (N)'	System	03 Dec 2020 00:00:05

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-12-02T17:59:59', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '93845536-aa9b-425f-a25f-754335ed7b39' User entered '02 Dec 2020 17:59:59'	System	03 Dec 2020 00:00:05
	System	03 Dec 2020 00:00:05

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[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)	02 May 2021 13:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-12-10T14:07:22', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '2c32b096-1a77-4f95-b95f-f51e6b3a30df' User entered 'No (N)'	System	10 Dec 2020 20:07:37
	System	10 Dec 2020 20:07:37

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

Have you been exposed to someone with 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)	02 May 2021 13:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-12-10T14:07:26', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '2c32b096-1a77-4f95-b95f-f51e6b3a30df' User entered 'No (N)'	System	10 Dec 2020 20:07:37
	System	10 Dec 2020 20:07:37

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-12-10T14:07:32', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '2c32b096-1a77-4f95-b95f-f51e6b3a30df' User entered '10 Dec 2020 14:07:32'	System	10 Dec 2020 20:07:37
	System	10 Dec 2020 20:07:37

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[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)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

Have you been exposed to someone with 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)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[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)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

Have you been exposed to someone with 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)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

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)	02 May 2021 13:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-12-30T18:36:22', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '862bbb14-7814-4f01-934f-e0413d2cb273'	System	31 Dec 2020 00:36:30
User entered 'No (N)'	System	31 Dec 2020 00:36:30

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

Have you been exposed to someone with 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)	02 May 2021 13:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-12-30T18:36:24', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '862bbb14-7814-4f01-934f-e0413d2cb273'	System	31 Dec 2020 00:36:30
User entered 'No (N)'	System	31 Dec 2020 00:36:30

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2020-12-30T18:36:27', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '862bbb14-7814-4f01-934f-e0413d2cb273' User entered '30 Dec 2020 18:36:27'	System	31 Dec 2020 00:36:30
	System	31 Dec 2020 00:36:30

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[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)	02 May 2021 13:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2021-01-07T20:39:30', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '300395dc-a141-4581-b3a0-1d0ac267b7e9' User entered 'No (N)'	System	08 Jan 2021 02:39:38
	System	08 Jan 2021 02:39:38

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Have you been exposed to someone with 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)	02 May 2021 13:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2021-01-07T20:39:32', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '300395dc-a141-4581-b3a0-1d0ac267b7e9' User entered 'No (N)'	System	08 Jan 2021 02:39:38
	System	08 Jan 2021 02:39:38

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D70A5B79-47CC-4659-B391-71DE154DE0A3)', Time: '2021-01-07T20:39:35', User OID: 'PatientReportedOutcome (US3252009)', ODM File OID: '300395dc-a141-4581-b3a0-1d0ac267b7e9' User entered '07 Jan 2021 20:39:35'	System	08 Jan 2021 02:39:38
	System	08 Jan 2021 02:39:38

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 12:09:22

US3252009

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:09:22
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 12:09:22

US3252009

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Shannon Moyer (b) (4)	11 Dec 2020 02:48:10
	(b) (4)	

US3252009

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Shannon Moyer (b) (4)	11 Dec 2020 02:48:10
	(b) (4)	

US3252009

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Shannon Moyer (b) (4)	11 Dec 2020 02:48:10
	(b) (4)	

US3252009

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered empty.	Shannon Moyer (b) (4)	11 Dec 2020 02:48:10
	(b) (4)	

US3252009

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	11 Dec 2020 02:48:15
	(b) (4)	

US3252009

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:45
User entered 'I'	System	11 Dec 2020 02:48:15

US3252009

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:40:12
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	11 Dec 2020 02:48:25
	(b) (4)	

US3252009

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:40:12
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered '10 Dec 2020'	Shannon Moyer (b) (4)	11 Dec 2020 02:48:25
	(b) (4)	

US3252009

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:40:12
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	11 Dec 2020 02:48:25
	(b) (4)	

US3252009

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:40:12
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Shannon Moyer (b) (4)	11 Dec 2020 02:48:25
	(b) (4)	

US3252009

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:40:12
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	11 Dec 2020 02:48:29
	(b) (4)	

US3252009

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:40:12
User entered 'I'	System	11 Dec 2020 02:48:29

US3252009

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:40:12
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	11 Jan 2021 05:12:10
	(b) (4)	

US3252009

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:40:12
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered '9 Jan 2021'	Shannon Moyer (b) (4)	11 Jan 2021 05:12:10
	(b) (4)	

US3252009

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:40:12
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4) (b) (4)	11 Jan 2021 05:12:10

US3252009

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:40:12
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Shannon Moyer (b) (4) (b) (4)	11 Jan 2021 05:12:10

US3252009

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:40:12
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	11 Jan 2021 05:12:14
	(b) (4)	

US3252009

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:40:12
User entered 'I'	System	11 Jan 2021 05:12:14

US3252009

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:47

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User closed query 'Per CDM: Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:34:39
Query 'Per CDM: Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 07:07:23
User opened query 'Per CDM: Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 15:46:28
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:06
User entered empty.	Joanna Gurrola Mahoney (b) (4)	01 Apr 2021 16:44:49

US3252009

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:47

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:43:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 07:05:46
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 07:05:46
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:06
User entered '0'	Joanna Gurrola Mahoney (b) (4)	01 Apr 2021 16:44:49

US3252009

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:47

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:06
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	01 Apr 2021 16:44:49

US3252009

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:47

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:43:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 07:05:46
User entered 'Amendment 5 (Amendment 5)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 07:05:46
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:06
User entered 'Amendment 6 or later (Amendment 6 or later)'	Joanna Gurrola Mahoney (b) (4)	01 Apr 2021 16:44:49

US3252009

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:47

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:06
User entered '13 Jan 2021'	Joanna Gurrola Mahoney (b) (4)	01 Apr 2021 16:44:49

US3252009

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:47

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:06
User entered 'Placebo (Placebo)'	Joanna Gurrola Mahoney (b) (4)	01 Apr 2021 16:44:49

US3252009

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:47

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:06
User entered 'Placebo (Placebo)'	Joanna Gurrola Mahoney (b) (4)	01 Apr 2021 16:44:49

US3252009

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:47

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:06
User entered 'Not Administered (NA)'	Joanna Gurrola Mahoney (b) (4)	01 Apr 2021 16:44:49

US3252009

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:47

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:06
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	01 Apr 2021 16:44:49

US3252009

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:47

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User entered '1'	System	01 Apr 2021 16:44:49

US3252009

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:47

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User entered empty.	System	01 Apr 2021 16:44:49

US3252009

Folder: Unscheduled 01 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:09:47

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:06:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:27:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '1 Sep 2020'	Uche Ehiemua (b) (4)	16 Sep 2020 15:19:17
	(b) (4)	

US3252009

Folder: Unscheduled 01 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:09:47

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:06:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:27:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '0'	Uche Ehiemua (b) (4)	16 Sep 2020 15:19:17
	(b) (4)	

US3252009

Folder: Unscheduled 01 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:09:47

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:06:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:27:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '0'	Uche Ehiemua (b) (4)	16 Sep 2020 15:19:17
	(b) (4)	

US3252009

Folder: Unscheduled 01 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:09:47

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:06:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:27:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '0'	Uche Ehiemua (b) (4)	16 Sep 2020 15:19:17
	(b) (4)	

US3252009

Folder: Unscheduled 01 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:09:47

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:06:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:27:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'I'	Uche Ehiemua (b) (4)	16 Sep 2020 15:19:17
	(b) (4)	

US3252009

Folder: Unscheduled 01 Sep 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:46
Data entry locked.	(b) (4), (b) (6)	28 Apr 2021 21:06:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:30:56
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Yes (Y)'	Uche Ehiemua (b) (4)	16 Sep 2020 15:21:05
	(b) (4)	

US3252009

Folder: Unscheduled 01 Sep 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:46
Data entry locked.	(b) (4), (b) (6)	28 Apr 2021 21:06:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:30:56
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '1 Sep 2020'	Uche Ehiemua (b) (4)	16 Sep 2020 15:21:05
	(b) (4)	

US3252009

Folder: Unscheduled 01 Sep 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:46
Data entry locked.	(b) (4), (b) (6)	28 Apr 2021 21:06:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:28
User closed query 'Source also states a urine pregnancy test was collected at 12:18. Please review and update as necessary. ' (Site from CRA).		12 Apr 2021 17:38:25
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:06
Query 'Source also states a urine pregnancy test was collected at 12:18. Please review and update as necessary. ' answered with 'updated' (Site from CRA).	mathew maran (b) (4)	25 Mar 2021 06:15:39
User entered 'Urine (URINE)' reason for change: Data Entry Error	mathew maran (b) (4)	25 Mar 2021 06:15:24
User entered 'Serum (SERUM)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 05:35:18
DataPoint Un-verified.		25 Mar 2021 05:34:26
Signature has been broken.		25 Mar 2021 05:34:26
User entered 'Urine (URINE)' reason for change: Data Entry Error		25 Mar 2021 05:34:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:30:56
User opened query 'Source also states a urine pregnancy test was collected at 12:18. Please review and update as necessary. ' (Site from CRA).		24 Mar 2021 15:30:52
Query 'Source also states a urine pregnancy test was performed. Please review and update as necessary. ' canceled (Site from CRA).		24 Mar 2021 15:29:40
User opened query 'Source also states a urine pregnancy test was performed. Please review and update as necessary. ' (Site from CRA).		24 Mar 2021 15:29:16
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'Serum (SERUM)'	Uche Ehiemua (b) (4)	16 Sep 2020 15:21:05
	(b) (4)	

US3252009

Folder: Unscheduled 01 Sep 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:46
Data entry locked.	(b) (4), (b) (6)	28 Apr 2021 21:06:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:30:56
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User closed query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	(b) (4), (b) (6)	31 Oct 2020 18:27:32
Query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' answered with 'Pregnancy test confirmed. Pregnancy form already submitted to IQVIA' (Site from System).	Uche Ehiemua (b) (4)	16 Sep 2020 15:22:18
User opened query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	System	16 Sep 2020 15:21:05
User entered 'Positive (POSITIVE)'	Uche Ehiemua (b) (4)	16 Sep 2020 15:21:05

US3252009

Folder: Unscheduled 01 Sep 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:46
Data entry locked.	(b) (4), (b) (6)	28 Apr 2021 21:06:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:30:56
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered 'No (N)'	Uche Ehiemua (b) (4)	16 Sep 2020 15:21:05
	(b) (4)	

US3252009

Folder: Unscheduled 01 Sep 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:46
Data entry locked.	(b) (4), (b) (6)	28 Apr 2021 21:06:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:30:56
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '1 Sep 2020'	Uche Ehiemua (b) (4)	16 Sep 2020 15:21:05
	(b) (4)	

US3252009

Folder: Unscheduled 01 Sep 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:46
Data entry locked.	(b) (4), (b) (6)	28 Apr 2021 21:06:57
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:06
User entered '12:18' reason for change: Data Entry Error	mathew maran (b) (4)	25 Mar 2021 06:15:24
User entered '12:30' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 05:35:18
DataPoint Un-verified.		25 Mar 2021 05:34:26
Signature has been broken.		25 Mar 2021 05:34:26
User entered '12:18' reason for change: Data Entry Error		25 Mar 2021 05:34:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:30:56
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:27:00
User entered '12:30'	Uche Ehiemua (b) (4)	16 Sep 2020 15:21:05
	(b) (4)	

US3252009

Folder: Unscheduled 01 Sep 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:46
User entered '1 Sep 2020 12:18'	System	25 Mar 2021 06:15:24
User entered '1 Sep 2020 12:30'	System	25 Mar 2021 05:35:18
User entered '1 Sep 2020 12:18'	System	25 Mar 2021 05:34:26
User entered '1 Sep 2020 12:30'	System	16 Sep 2020 15:21:05

US3252009

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:09:47

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:37:00
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:09:47

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 23:10:50
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:37:42

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORGESTIMATE, PRODUCTSYNONYM: TRINESSA LO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 08:41:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 08:41:32
Data point term sent to Coder	System	29 Dec 2020 07:17:54
User entered 'TRINESSA LO (0.18/0.25 mg)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	29 Dec 2020 07:17:13
Data point term sent to Coder	System	29 Dec 2020 07:16:54
Coding entries removed.	Shannon Moyer (b) (4)	29 Dec 2020 07:16:47
User entered 'TRINESSA LO (0.18/0.25)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	29 Dec 2020 07:16:47
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORGESTIMATE, PRODUCTSYNONYM: TRINESSA LO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 10:46:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 10:46:41
Data point term sent to Coder	System	20 Aug 2020 23:12:15
User entered 'Trinessa Lo'	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 23:11:51

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Yes (Y)'	Joanna Gurrola Mahoney	20 Aug 2020 23:11:51
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Contraceptive'	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 23:11:51

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (0.180/0.025). Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:01:42
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (0.180/0.025). Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	Shannon Moyer (b) (4)	29 Dec 2020 07:17:20
User entered '1' reason for change: Data Entry Error	Shannon Moyer (b) (4)	29 Dec 2020 07:16:47
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (0.180/0.025). Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 13:38:20
User closed query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this combination medication. Please correct the dosage with the corresponding dose unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:15:04
Query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this combination medication. Please correct the dosage with the corresponding dose unit as appropriate.' answered with 'corrected dose.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	23 Oct 2020 18:13:24
User entered '0.18/0.25' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Oct 2020 18:13:07
User opened query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this combination medication. Please correct the dosage with the corresponding dose unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 07:49:16
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 07:49:16

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:47

[Dose per administration](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable' answered with 'UPDATED' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	16 Sep 2020 20:41:46
User entered '0.180/0.025' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	16 Sep 2020 20:41:34
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 14:11:41
User entered '0.025'	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 23:11:51

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'tablet (TABLET)' reason for change:	Shannon Moyer (b) (4)	29 Dec 2020 07:16:47
Data Entry Error	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Oct 2020 18:13:07
User entered 'mg (mg)'	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 23:11:51

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Joanna Gurrola Mahoney	20 Aug 2020 23:11:51
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'once daily (QD)'	Joanna Gurrola Mahoney	20 Aug 2020 23:11:51
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 23:11:51

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Oral (ORAL)'	Joanna Gurrola Mahoney	20 Aug 2020 23:11:51
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Joanna Gurrola Mahoney	20 Aug 2020 23:11:51
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:51:05
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Per source, correct as is' (Site from System).	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 23:12:04
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 23:11:51
User entered 'un Apr 2020'	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 23:11:51

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered '0'	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 23:11:51

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Yes (Y)'	Joanna Gurrola Mahoney	20 Aug 2020 23:11:51
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Joanna Gurrola Mahoney	20 Aug 2020 23:11:51
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 23:11:51

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User entered '1'	System	20 Aug 2020 23:11:51

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User entered '1'	System	20 Aug 2020 23:11:51

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User entered '804 (804)'	System	20 Aug 2020 23:11:51

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: COMBINATIONS OF VITAMINS, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 14:28:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 14:28:17
Data point term sent to Coder	System	29 Dec 2020 07:18:55
Coding entries removed.	Shannon Moyer (b) (4)	29 Dec 2020 07:18:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 23:27:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 23:27:01
Data point term sent to Coder	System	23 Oct 2020 18:15:51
Data point term sent to Coder	System	26 Sep 2020 07:28:46
User entered 'Nature Made Prenatal Multivitamin + 200mg DHA'	Nancy Torrence (b) (4)	26 Sep 2020 07:28:03

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User closed query 'Per CDM RQ: Per previous query response "Updated"; however, the update is not obvious please provide location of update such as data field updated. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 18:08:12
Query 'Per CDM RQ: Per previous query response "Updated"; however, the update is not obvious please provide location of update such as data field updated. Thank you. ' answered with 'updated.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	08 Jan 2021 16:32:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	08 Jan 2021 16:31:58
User opened query 'Per CDM RQ: Per previous query response "Updated"; however, the update is not obvious please provide location of update such as data field updated. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:03:07
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:02:28
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	29 Dec 2020 07:18:29
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 13:40:29
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	26 Sep 2020 07:28:03

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'pregnancy' reason for change: Data Entry Error	Shannon Moyer (b) (4)	29 Dec 2020 07:18:18
User closed query 'Per DM CLR: Please verify Con Med indication and update to reflect the underlying medical condition that this Con Med is being used to treat or prevent as appropriate. Please reconcile with Med History or AE eCRF as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please verify Con Med indication and update to reflect the underlying medical condition that this Con Med is being used to treat or prevent as appropriate. Please reconcile with Med History or AE eCRF as appropriate.' answered with 'Patient taking them for pregnancy. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 13:20:55
Query 'Per DM CLR: Please verify Con Med indication and update to reflect the underlying medical condition that this Con Med is being used to treat or prevent as appropriate. Please reconcile with Med History or AE eCRF as appropriate.' answered with 'Patient taking them for pregnancy. ' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	23 Oct 2020 18:19:12
User entered 'prenatal vitamins' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Oct 2020 18:14:55
User opened query 'Per DM CLR: Please verify Con Med indication and update to reflect the underlying medical condition that this Con Med is being used to treat or prevent as appropriate. Please reconcile with Med History or AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 07:48:30
User entered 'Pregnancy'	Nancy Torrence (b) (4)	26 Sep 2020 07:28:03
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'I'	Nancy Torrence (b) (4)	26 Sep 2020 07:28:03
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'tablet (TABLET)'	Nancy Torrence (b) (4)	26 Sep 2020 07:28:03
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Nancy Torrence (b) (4)	26 Sep 2020 07:28:03
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'once daily (QD)'	Nancy Torrence (b) (4)	26 Sep 2020 07:28:03
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Nancy Torrence (b) (4)	26 Sep 2020 07:28:03
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Oral (ORAL)'	Nancy Torrence (b) (4)	26 Sep 2020 07:28:03
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Nancy Torrence (b) (4)	26 Sep 2020 07:28:03
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered '14 Sep 2020'	Nancy Torrence (b) (4)	26 Sep 2020 07:28:03
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered '0'	Nancy Torrence (b) (4)	26 Sep 2020 07:28:03
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	26 Sep 2020 07:28:03
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Nancy Torrence (b) (4)	26 Sep 2020 07:28:03
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'No (N)'	Nancy Torrence (b) (4)	26 Sep 2020 07:28:03
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User entered '1'	System	26 Sep 2020 07:28:03

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User entered '1'	System	26 Sep 2020 07:28:03

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User entered '804 (804)'	System	26 Sep 2020 07:28:03

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:23
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 07:30:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 07:30:43
Data point term sent to Coder	System	26 Sep 2020 07:29:47
User entered 'Flu Vaccine'	Nancy Torrence (b) (4) (b) (4)	26 Sep 2020 07:29:43

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:23
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	26 Sep 2020 07:29:43
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:23
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Flu Vaccine'	Nancy Torrence (b) (4)	26 Sep 2020 07:29:43
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:23
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'I'	Nancy Torrence (b) (4)	26 Sep 2020 07:29:43
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:23
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Other (OTHER)'	Nancy Torrence (b) (4)	26 Sep 2020 07:29:43
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:23
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'SHOT'	Nancy Torrence (b) (4)	26 Sep 2020 07:29:43
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:23
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'once (ONCE)'	Nancy Torrence (b) (4)	26 Sep 2020 07:29:43
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:23
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Nancy Torrence (b) (4)	26 Sep 2020 07:29:43
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:23
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Intramuscular (INTRAMUSCULAR)'	Nancy Torrence (b) (4)	26 Sep 2020 07:29:43
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:23
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Nancy Torrence (b) (4)	26 Sep 2020 07:29:43
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:23
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered '16 Sep 2020'	Nancy Torrence (b) (4)	26 Sep 2020 07:29:43
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:23
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered '0'	Nancy Torrence (b) (4)	26 Sep 2020 07:29:43
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:23
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'No (N)'	Nancy Torrence (b) (4)	26 Sep 2020 07:29:43
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:23
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered '16 Sep 2020'	Nancy Torrence (b) (4)	26 Sep 2020 07:29:43
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:23
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'No (N)'	Nancy Torrence (b) (4)	26 Sep 2020 07:29:43
	(b) (4)	

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:23
User entered empty.	System	26 Sep 2020 07:29:43

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:23
User entered empty.	System	26 Sep 2020 07:29:43

US3252009

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:23
User entered empty.	System	26 Sep 2020 07:29:43

US3252009

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:09:47

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:47:31
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'No (N)'	Shannon Moyer (b) (4)	05 Aug 2020 02:38:10
	(b) (4)	

US3252009

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:09:47

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:01:51
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered '11 Sep 2020'	Uche Ehiemua (b) (4)	13 Jan 2021 23:25:15
	(b) (4)	

US3252009

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:09:47

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:01:51
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Pregnancy (PREGNANCY)'	Uche Ehiemua (b) (4)	13 Jan 2021 23:25:15
	(b) (4)	

US3252009

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:09:47

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:01:51
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Uche Ehiemua (b) (4)	13 Jan 2021 23:25:15
	(b) (4)	

US3252009

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:09:47

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:01:51
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered '13 Jan 2021'	Uche Ehiemua (b) (4)	13 Jan 2021 23:28:35
	(b) (4)	

US3252009

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:09:47

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:01:51
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:43:13
User closed query 'Per CDM : Per CCGs, relocation should be listed other OTHER as reason for discontinuation. Please verify and amend. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 09:34:59
Query 'Per CDM : Per CCGs, relocation should be listed other OTHER as reason for discontinuation. Please verify and amend. Thank you' answered with 'has been updated to match' (Site from DM).	Xavier Morales (b) (4)	19 Apr 2021 21:57:01
Signature has been broken.	Xavier Morales (b) (4)	19 Apr 2021 21:56:42
User entered 'Other (OTHER)' reason for change: Data Entry Error	Xavier Morales (b) (4)	19 Apr 2021 21:56:42
User opened query 'Per CDM : Per CCGs, relocation should be listed other OTHER as reason for discontinuation. Please verify and amend. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 09:06:53
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Uche Ehiemua (b) (4)	13 Jan 2021 23:28:35

US3252009

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:09:47

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:01:51
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:43:13
Signature has been broken.	Xavier Morales (b) (4)	19 Apr 2021 21:56:42
User entered 'PATIENT REQUESTED TO BE UNBLINDED FROM STUDY DUE TO MOVING TO A DIFFERENT STATE, MINNESOTA. PATIENT STATES SHE CAN NO LONGER MAKE SITE VISITS.' reason for change: Data Entry Error	Xavier Morales (b) (4)	19 Apr 2021 21:56:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered 'Patient requested to be unblinded from study due to moving to a different state, Minnesota. Patient states she can longer make site visits.'	Uche Ehiemua (b) (4)	13 Jan 2021 23:28:35

US3252009

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:09:47

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:01:51
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Uche Ehiemua (b) (4)	13 Jan 2021 23:28:35
	(b) (4)	

US3252009

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:09:47

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:01:51
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Uche Ehiemua (b) (4)	13 Jan 2021 23:28:35
	(b) (4)	

US3252009

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:09:47

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:01:51
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Uche Ehiemua (b) (4)	13 Jan 2021 23:28:35
	(b) (4)	

US3252009

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:09:47

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:01:51
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:26:57
User entered empty.	Uche Ehiemua (b) (4)	13 Jan 2021 23:28:35
	(b) (4)	