

US3252516 (Prod: Centex Studies Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:14:45

All time stamps listed in this document are displayed in GMT

US3252516

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 22:09:26

Generated On: 09 Jun 2021 16:14:45

Participant ID

US3252516

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

US3252516

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 21 SEP 2020

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

Folder OID SCRN

US3252516

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Date of Birth (MMM yyyy)	(b) (6) 1980
Age	40
Age Units	YEARS
Age (Derived)	40
Sex	Female <input type="radio"/> Male <input checked="" 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	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	HISPANIC
Unknown	False
Not reported	False

US3252516

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Date of Informed Consent (*dd MMM yyyy*) 21 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version
Amendment 1
Amendment 2
Amendment 3
Amendment 4
Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail
Withdrew Consent
Inclusion/Exclusion
Cohort Full
Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3252516

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Did the participant meet all eligibility criteria?

Yes

No

US3252516

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Were any significant conditions reported?

Yes

No

US3252516

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

Condition	SEIZURE DISORDER
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3252516

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:28 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 11:28
Height (<i>xxx.x</i>)	67 in
Weight (<i>xxx.x</i>)	164 lb
BMI (<i>xxx.x</i>)	25.73974 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)	_____

US3252516

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3252516

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

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 CURRENTLY NOT WORKING.

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3252516

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

US3252516

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 03:09:06

Generated On: 09 Jun 2021 16:14:45

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 21 SEP 2020

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

Folder OID VISIT1

US3252516

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Mar 2021 03:09:06

Generated On: 09 Jun 2021 16:14:45

What was the date of randomization? (dd MMM yyyy) 21 SEP 2020

What was the participant's randomization number? 146657

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

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

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

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

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

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

Liver Disease Yes No

Human Immunodeficiency Virus (HIV) infection Yes No

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 03:09:06

Generated On: 09 Jun 2021 16:14:45

Height	ND - Not Done
Weight	ND - Not Done

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 03:09:06

Generated On: 09 Jun 2021 16:14:45

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:28 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 11:28
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	85 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 03:09:06

Generated On: 09 Jun 2021 16:14:45

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:29 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 13:29
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	120 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3252516

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 03:09:06

Generated On: 09 Jun 2021 16:14:45

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.

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 03:09:06

Generated On: 09 Jun 2021 16:14:45

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 12:59 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 12:59

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

US3252516

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 03:09:06

Generated On: 09 Jun 2021 16:14:45

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 21 SEP 2020

Collection time (*00:00-23:59*) 12:11 (24 HR)

Collection date and time (derived) 21 SEP 2020 12:11

US3252516

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Collection date (<i>dd MMM yyyy</i>)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:07	21 SEP 2020 12:07
Nasopharyngeal Swab 2	No		

US3252516

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

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 97.8 °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 21 SEP 2020 13:47

PC Open Date & Time 21 SEP 2020 13:19

PC Close Date & Time 21 SEP 2020 15:49

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

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 98.6 °F

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

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

PC Time Stamp 21 SEP 2020 19:09
PC Open Date & Time 21 SEP 2020 16:44
PC Close Date & Time 22 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:45

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	22 SEP 2020 20:47
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	23 SEP 2020 19:40
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	24 SEP 2020 19:48
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp 26 SEP 2020 01:03

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

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

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

PC Time Stamp	26 SEP 2020 15:33
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	28 SEP 2020 04:07
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

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

21 SEP 2020 13:48

PC Open Date & Time

21 SEP 2020 13:19

PC Close Date & Time

21 SEP 2020 15:49

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

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

21 SEP 2020 19:09

PC Open Date & Time

21 SEP 2020 16:44

PC Close Date & Time

22 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 2

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

22 SEP 2020 20:48

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 3

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

23 SEP 2020 19:41

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

24 SEP 2020 19:49

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

26 SEP 2020 01:04

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

26 SEP 2020 15:34

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

28 SEP 2020 04:07

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

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

No

Yes

PC Time stamp	21 SEP 2020 13:48
PC Open Date & Time	21 SEP 2020 13:19
PC Close Date & Time	21 SEP 2020 15:49

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

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

No

Yes

PC Time stamp	21 SEP 2020 19:10
PC Open Date & Time	21 SEP 2020 16:44
PC Close Date & Time	22 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

	Yes <input type="checkbox"/>
PC Time stamp	22 SEP 2020 20:48
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

	Yes <input type="checkbox"/>
PC Time stamp	23 SEP 2020 19:41
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

	Yes <input type="checkbox"/>
PC Time stamp	24 SEP 2020 19:50
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

	Yes <input type="checkbox"/>
PC Time stamp	26 SEP 2020 01:04
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

	Yes <input type="checkbox"/>
PC Time stamp	26 SEP 2020 15:35
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

	Yes <input type="checkbox"/>
PC Time stamp	28 SEP 2020 04:08
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3252516

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3252516

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252516

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 05 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3252516

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252516

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 12 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3252516

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252516

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 03:09:06

Generated On: 09 Jun 2021 16:14:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 03:09:06

Generated On: 09 Jun 2021 16:14:45

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:19 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 11:19
Temperature (<i>xxx.x</i>)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	84 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	94 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 03:09:06

Generated On: 09 Jun 2021 16:14:45

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:21 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 12:21
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3252516

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 03:09:06

Generated On: 09 Jun 2021 16:14:45

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.

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 03:09:06

Generated On: 09 Jun 2021 16:14:45

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 11:51 (24 HR)

Treatment Date and Time (derived) 20 OCT 2020 11:51

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

US3252516

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 03:09:06

Generated On: 09 Jun 2021 16:14:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	20 OCT 2020
Collection time (<i>00:00-23:59</i>)	11:43 (24 HR)
Collection date and time (derived)	20 OCT 2020 11:43

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 03:09:06

Generated On: 09 Jun 2021 16:14:45

Collection date (<i>dd MMM yyyy</i>)			20 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:24	20 OCT 2020 11:24
Nasopharyngeal Swab 2	No		

US3252516

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:09:06

Generated On: 09 Jun 2021 16:14:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

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

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

20 OCT 2020 12:11

PC Close Date & Time

20 OCT 2020 14:41

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

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**

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 20 OCT 2020 15:36

PC Close Date & Time 21 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.5 °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 22 OCT 2020 11:39

PC Open Date & Time 21 OCT 2020 12:00

PC Close Date & Time 22 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:45

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 98.7 °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 23 OCT 2020 09:58

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:45

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 23 OCT 2020 12:00
PC Close Date & Time 24 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	25 OCT 2020 07:36
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	26 OCT 2020 09:46
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	27 OCT 2020 08:05
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

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

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.**

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

PC Open Date & Time

20 OCT 2020 12:11

PC Close Date & Time

20 OCT 2020 14:41

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

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

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.**

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

PC Open Date & Time

20 OCT 2020 15:36

PC Close Date & Time

21 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 2

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

Please select one response below

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

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

- Yes
- No

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.**

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

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 3

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

Please select one response below

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

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

- Yes
- No

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.**

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

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 4

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

Please select one response below

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

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

- Yes
- No

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.**

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

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 5

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

Please select one response below

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

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

- Yes
- No

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.**

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

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

26 OCT 2020 09:46

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

27 OCT 2020 08:04

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

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

No
Yes

PC Time stamp

PC Open Date & Time

20 OCT 2020 12:11

PC Close Date & Time

20 OCT 2020 14:41

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

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

No

Yes

PC Time stamp

PC Open Date & Time

20 OCT 2020 15:36

PC Close Date & Time

21 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

Yes

PC Time stamp

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

Yes

PC Time stamp

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

Yes

PC Time stamp

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

Yes

PC Time stamp

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

	Yes <input type="radio"/>
PC Time stamp	26 OCT 2020 09:47
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

	Yes <input type="checkbox"/>
PC Time stamp	27 OCT 2020 08:05
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3252516

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 27 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3252516

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252516

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 3 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3252516

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252516

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 10 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3252516

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:09:01

Generated On: 09 Jun 2021 16:14:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252516

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 03:09:07

Generated On: 09 Jun 2021 16:14:45

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 17 NOV 2020

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

Folder OID VISIT3

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 03:09:07

Generated On: 09 Jun 2021 16:14:45

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) 17 NOV 2020

Time of assessment (*00:00-23:59*) 10:31 (24 HR)

Vital Signs Date and Time (derived) 17 NOV 2020 10:31

Temperature (*xxx.x*) 98.3 F

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) 82 beats/min

Pulse units BPM

Respiratory Rate (*xxx*) 15 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) 112 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) 74 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3252516

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 03:09:06

Generated On: 09 Jun 2021 16:14:45

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.

US3252516

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 03:09:06

Generated On: 09 Jun 2021 16:14:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	17 NOV 2020
Collection time (<i>00:00-23:59</i>)	10:53 (24 HR)
Collection date and time (derived)	17 NOV 2020 10:53

US3252516

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:09:06

Generated On: 09 Jun 2021 16:14:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 61

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

No

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 22 NOV 2020 16:23:12

Patient Cloud Open Date & Time 18 NOV 2020 00:01

Patient Cloud Close Date & Time 22 NOV 2020 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 68

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

No

Yes

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

No

Yes

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

Date and time of submission 25 NOV 2020 10:58:32

Patient Cloud Open Date & Time 25 NOV 2020 00:01

Patient Cloud Close Date & Time 29 NOV 2020 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 75

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

No

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 11:54:05

Patient Cloud Open Date & Time 02 DEC 2020 00:01

Patient Cloud Close Date & Time 06 DEC 2020 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 DEC 2020 12:00:56
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 89

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

No

Yes

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

No

Yes

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

Date and time of submission 17 DEC 2020 19:27:04

Patient Cloud Open Date & Time 16 DEC 2020 00:01

Patient Cloud Close Date & Time 20 DEC 2020 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 96

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 103

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

No

Yes

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

No

Yes

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

Date and time of submission 31 DEC 2020 19:09:29

Patient Cloud Open Date & Time 30 DEC 2020 00:01

Patient Cloud Close Date & Time 03 JAN 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 110

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 117

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 19:21:11
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 131

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 138

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 03 FEB 2021 00:01

[Patient Cloud Close Date & Time](#) 07 FEB 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 145

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 159

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	12 MAR 2021 00:07:20
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" 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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	19 MAR 2021 11:03:18
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 187

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 194

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 201

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 APR 2021 13:40:52
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 215

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

No

Yes

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

No

Yes

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

Date and time of submission 23 APR 2021 19:43:04

Patient Cloud Open Date & Time 21 APR 2021 00:01

Patient Cloud Close Date & Time 25 APR 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 222

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 236

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	12 MAY 2021 00:01
Patient Cloud Close Date & Time	16 MAY 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 243

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 250

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	26 MAY 2021 00:01
Patient Cloud Close Date & Time	30 MAY 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	02 JUN 2021 00:01
Patient Cloud Close Date & Time	06 JUN 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 264

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	20 JUN 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2021 00:01
Patient Cloud Close Date & Time	04 JUL 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 320

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	04 AUG 2021 00:01
Patient Cloud Close Date & Time	08 AUG 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 341

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	29 AUG 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	08 SEP 2021 00:01
Patient Cloud Close Date & Time	12 SEP 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2021 00:01
Patient Cloud Close Date & Time	19 SEP 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2021 00:01
Patient Cloud Close Date & Time	26 SEP 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2021 00:01
Patient Cloud Close Date & Time	03 OCT 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2021 00:01
Patient Cloud Close Date & Time	10 OCT 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 17 OCT 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2021 00:01
Patient Cloud Close Date & Time	24 OCT 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 411

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	10 NOV 2021 00:01
Patient Cloud Close Date & Time	14 NOV 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	17 NOV 2021 00:01
Patient Cloud Close Date & Time	21 NOV 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	24 NOV 2021 00:01
Patient Cloud Close Date & Time	28 NOV 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 05 DEC 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 12 DEC 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	15 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 460

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	22 DEC 2021 00:01
Patient Cloud Close Date & Time	26 DEC 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	05 JAN 2022 00:01
Patient Cloud Close Date & Time	09 JAN 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	12 JAN 2022 00:01
Patient Cloud Close Date & Time	16 JAN 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	19 JAN 2022 00:01
Patient Cloud Close Date & Time	23 JAN 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	02 FEB 2022 00:01
Patient Cloud Close Date & Time	06 FEB 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#) 13 FEB 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	27 FEB 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#) 06 MAR 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	27 MAR 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	06 APR 2022 00:01
Patient Cloud Close Date & Time	10 APR 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission	
Patient Cloud Open Date & Time	20 APR 2022 00:01
Patient Cloud Close Date & Time	24 APR 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 600

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	22 MAY 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 628

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

Patient Cloud Open Date & Time	08 JUN 2022 00:01
Patient Cloud Close Date & Time	12 JUN 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 635

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 642

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

Patient Cloud Open Date & Time	22 JUN 2022 00:01
Patient Cloud Close Date & Time	26 JUN 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 649

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 656

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	06 JUL 2022 00:01
Patient Cloud Close Date & Time	10 JUL 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	13 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 670

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 684

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 691

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	10 AUG 2022 00:01
Patient Cloud Close Date & Time	14 AUG 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 698

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 712

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 719

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	07 SEP 2022 00:01
Patient Cloud Close Date & Time	11 SEP 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 726

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	21 SEP 2022 00:01
Patient Cloud Close Date & Time	25 SEP 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 740

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	28 SEP 2022 00:01
Patient Cloud Close Date & Time	02 OCT 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 747

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)
- Chills
- Cough
- Shortness of breath
- Difficulty breathing
- Fatigue
- Muscle aches
- Body aches
- Headache
- New loss of taste
- New loss of smell
- Sore throat
- Congestion
- Runny nose
- Nausea
- Vomiting
- Diarrhea

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission	
Patient Cloud Open Date & Time	19 OCT 2022 00:01
Patient Cloud Close Date & Time	23 OCT 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 768

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)
- Chills
- Cough
- Shortness of breath
- Difficulty breathing
- Fatigue
- Muscle aches
- Body aches
- Headache
- New loss of taste
- New loss of smell
- Sore throat
- Congestion
- Runny nose
- Nausea
- Vomiting
- Diarrhea

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2022 00:01
Patient Cloud Close Date & Time	20 NOV 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2022 00:01
Patient Cloud Close Date & Time	27 NOV 2022 23:59

US3252516

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:14:45

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		08 MAR 2021 20:39:27

US3252516

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:09:26

Generated On: 09 Jun 2021 16:14:45

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 _____

US3252516

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:09:26

Generated On: 09 Jun 2021 16:14:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252516

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:09:26

Generated On: 09 Jun 2021 16:14:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 23 JAN 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3252516

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:40:39

Generated On: 09 Jun 2021 16:14:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252516

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:09:26

Generated On: 09 Jun 2021 16:14:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 20 FEB 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3252516

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:09:26

Generated On: 09 Jun 2021 16:14:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252516

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:40:39

Generated On: 09 Jun 2021 16:14:45

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 19 MAR 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3252516

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:40:39

Generated On: 09 Jun 2021 16:14:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252516

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 19:04:16

Generated On: 09 Jun 2021 16:14:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3252516

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 19:04:16

Generated On: 09 Jun 2021 16:14:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 APR 2021
Time of assessment (<i>00:00-23:59</i>)	11:03 (24 HR)
Vital Signs Date and Time (derived)	17 APR 2021 11:03
Temperature (<i>xxx.x</i>)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3252516

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 19:04:16

Generated On: 09 Jun 2021 16:14:45

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.

US3252516

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 19:04:16

Generated On: 09 Jun 2021 16:14:45

Was the sample collected? Yes
No

Collection date (dd MMM yyyy) _____

Collection time (00:00-23:59) _____

Collection date and time (derived) _____

US3252516

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 19:04:16

Generated On: 09 Jun 2021 16:14:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3252516

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

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 _____

US3252516

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3252516

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:14:45

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3252516

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:14:45

Generate Next COVID-19 Assessment

Yes

No

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 19:04:15

Generated On: 09 Jun 2021 16:14:45

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 17 APR 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID UNBLND_DECIDE

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 19:04:15

Generated On: 09 Jun 2021 16:14:45

Date of updated informed consent (*dd MMM yyyy*) 17 APR 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes
No

Under what version of the Protocol was the Participant unblinded? Amendment 5
Amendment 6 or later

Date of unblinding (*dd MMM yyyy*) 17 APR 2021

Participant randomization assignment mRNA-1273
Placebo

Actual Dose 1 mRNA-1273
Placebo
Not Administered

Actual Dose 2 mRNA-1273
Placebo
Not Administered

Will participant receive mRNA-1273? Yes
No

Placebo Only Flag _____

Continuing with mRNA-1273 _____

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 19:04:15

Generated On: 09 Jun 2021 16:14:45

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 17 APR 2021

Collection time (*00:00-23:59*) 11:42 (24 HR)

Collection date and time (derived) 17 APR 2021 11:42

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Apr 2021 19:04:15

Generated On: 09 Jun 2021 16:14:45

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 17 APR 2021

Collection time (*00:00 - 23:59*) 11:42

Collection Date and Time (derived) 17 APR 2021 11:42

US3252516

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 22:09:26

Generated On: 09 Jun 2021 16:14:45

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

AEID	USA-US108-2020-MRNA-1273-P30 1000004
Adverse event	ACUTE COLITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 SEP 2020
Start time (00:00-23:59)	00:00 (24 HR)
AE start date and time (derived)	30 SEP 2020 00:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	30 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	10 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

340 of 2601

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

DURING D22 SAFETY PHONE
CALL ON 12-OCT-2020 MR.
SUBJECT REPORTED A RECENT
HOSPITALIZATION. HE
REPORTS BEING DIAGNOSED
WITH COLITIS ON 30-SEP-2020
AND WAS HOSPITALIZED FOR
A TOTAL OF NINE DAYS.
PATIENT WAS REPORTEDLY
DISCHARGED FROM VALLEY
REGIONAL MEDICAL CENTER
ON 08-OCT-2020 AND WAS
GIVEN A PRESCRIPTION FOR
METRONIDAZOLE 500 MG TID
AND LEVOFLOXACIN 500 MG
ONCE A DAY. PATIENT
STARTED BOTH OF THESE
MEDICATIONS YESTERDAY ON
11-OCT-2020. PATIENT WAS
SENT A MEDICAL RELEASE
FORM VIA EMAIL IN ORDER TO
OBTAIN RECORDS FROM HIS
HOSPITALIZATION. WILL
CONTINUE TO UPDATE
INFORMATION AS IT BECOMES
AVAILABLE.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

AEID USA-US108-2020-MRNA-1273-P30
1000004

Adverse event BILATERAL MULTIFOCAL
PNEUMONIA RIGHT GREATER
THAN LEFT DUE TO
MYCOPLASMA PNEUMONIA

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) 30 SEP 2020

Start time (00:00-23:59) _____

AE start date and time (derived) _____

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 20 OCT 2020

End time (00:00-23:59) _____

AE End Date and Time (derived) _____

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 30 SEP 2020

Hospital Discharge Date (dd MMM yyyy) 10 OCT 2020

Admitted to ICU? Yes
No

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

	Unknown	<input type="radio"/>
Number of Days in ICU		
Persistent or significant disability or incapacity		False
Congenital anomaly or birth defect		False
Other medically important event		False
Relationship to investigational product	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
Action taken with investigational product	None	<input checked="" type="radio"/>
	Dose Delayed	<input type="radio"/>
	Investigational Product	<input type="radio"/>
	Withdrawn	<input type="radio"/>
	Not Applicable	<input type="radio"/>
Other action taken (check all that apply)		
None		False
Concomitant Medication		True
Concomitant Procedure		False
Outcome	Fatal	<input type="radio"/>
	Not Recovered/Not Resolved	<input type="radio"/>
	Recovered/Resolved	<input checked="" type="radio"/>
	Recovered/Resolved with Sequelae	<input type="radio"/>
	Recovering/Resolving	<input type="radio"/>
	Unknown	<input type="radio"/>

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

DURING D22 SAFETY CALL ON THE 12TH OF OCT 2020 SUBJECT REPORTED HE WAS RECENTLY HOSPITALIZED ON THE 30TH OF SEP 2020 AND DISCHARGE ON THE 8TH OF OCT 2020. SUBJECT PRESENTED TO HIS LOCAL EMERGENCY DEPARTMENT DUE TO A THREE-DAY HISTORY OF WATER STOOL, COUGH, AND SHORTNESS OF BREATH ON THE 30TH OF SEP 2020. SUBJECT WAS DIAGNOSES WITH PNEUMONIA, HYPOXEMIA AND COLITIS. SUBJECT WAS ADMITTED TO THE HOSPITAL FOR TREATMENT AND DISCHARGE ON OCT 8TH 2020 ONCE HIS SYMPTOMS RESOLVED. SUBJECT WAS STARTED ON LEVOFLOXACIN 500MG ONCE DAILY AND METRONIDAZOLE 500 MG THREE TIMES DAILY FOR THE NEXT FIVE DAYS. SUBJECT REPORTS HE STARTED THE MEDICATIONS ON THE 11TH OF OCT 2020.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

AEID USA-US108-2021-MRNA-1273-P30
1000020

Adverse event IRREGULAR HEART BEAT

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) UN APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) UN APR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 05 APR 2021

Hospital Discharge Date (dd MMM yyyy) 13 APR 2021

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU

PRODUCTION RELEASE (v12.003
EAB) (1725)

346 of 2601

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

AEID USA-US108-2021-MRNA-1273-P30
1000020

Adverse event IRREGULAR HEART BEAT

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) UN APR 2021

Start time (00:00-23:59) 00:00 (24 HR)

AE start date and time (derived) UN APR 2021 00:00

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) UN APR 2021

End time (00:00-23:59) _____

AE End Date and Time (derived) _____

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) _____

Hospital Discharge Date (dd MMM yyyy) _____

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU _____

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

AEID USA-US108-2020-MRNA-1273-P30
1000004

Adverse event HYPOXEMIA RESPIRATORY
FAILURE ON ADMISSION,
RESOLVED

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) 30 SEP 2020

Start time (00:00-23:59) _____

AE start date and time (derived) _____

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 10 OCT 2020

End time (00:00-23:59) _____

AE End Date and Time (derived) _____

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 30 SEP 2020

Hospital Discharge Date (dd MMM yyyy) 10 OCT 2020

Admitted to ICU? Yes
No
Unknown

PRODUCTION RELEASE (v12.003 350 of 2601
EAB) (1725)

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

AEID

Adverse event

SMALL BILATERAL PLEURAL
EFFUSIONS

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes

No

Start date (dd MMM yyyy)

30 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

10 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

True

Hospital Admission Date (dd MMM yyyy)

30 SEP 2020

Hospital Discharge Date (dd MMM yyyy)

10 OCT 2020

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

PRODUCTION RELEASE (v12.003

352 of 2601

EAB) (1725)

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 22:09:26

Generated On: 09 Jun 2021 16:14:45

Were any prior/concomitant medications and/or vaccinations taken?

Yes

No

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication PROPANOLOL

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

355 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication JANUVIA

Prophylaxis Yes
No

Indication TYPE II DIABETES MELLITUS

Dose per administration 50

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)

357 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication METRONIDAZOLE

Prophylaxis Yes
No

Indication COLITIS

Dose per administration 500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

359 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

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*) 11 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 20 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication LEVOFLOXACIN

Prophylaxis Yes
No

Indication COLITIS,PNEUMONIA

Dose per administration 500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

361 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

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*) 11 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 20 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication TRAZADONE

Prophylaxis Yes
No

Indication INSOMNIA

Dose per administration 200

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)

363 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

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 2010

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 10 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication KEPPRA

Prophylaxis Yes
No

Indication SEIZURES

Dose per administration 500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

365 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 30 SEP 2014

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication TRAMADOL

Prophylaxis Yes
No

Indication GENERALIZED PAIN

Dose per administration 50

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)

367 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 30 SEP 2016

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication LIBRIUM
(CHLORDIAZEPOXIDE)

Prophylaxis Yes
No

Indication ALCOHOL WITHDRAWAL
SYMPTOMS

Dose per administration 5

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)

369 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

	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)	30 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)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication TRAZODONE

Prophylaxis Yes
No

Indication INSOMNIA

Dose per administration 100

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

371 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

	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 APR 2020

Start date completely unknown _____ False

Ongoing? _____ Yes

_____ No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? _____ Yes

_____ No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) _____ 802

_____ 803

_____ 804

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication PROTONIX

Prophylaxis Yes
No

Indication GASTROESOPHAGEAL REFLUX DISEASE

Dose per administration 40

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)

373 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

	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) 16 APR 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication ZITHROMAX TAB

Prophylaxis Yes
No

Indication BILATERAL MULTIFOCAL
PNEUMONIA RIGHT GREATER
THAN LEFT DUE TO
MYCOPLASMA PNEUMONIA

Dose per administration 250

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

375 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 01 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 04 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication ZITHROMAX

Prophylaxis Yes
No

Indication BILATERAL MULTIFOCAL
PNEUMONIA RIGHT GREATER
THAN LEFT DUE TO
MYCOPLASMA PNEUMONIA

Dose per administration 500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous

PRODUCTION RELEASE (v12.003
EAB) (1725)

377 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 30 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 30 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication DEXAMETHASONE

Prophylaxis Yes
No

Indication BILATERAL MULTIFOCAL
PNEUMONIA RIGHT GREATER
THAN LEFT DUE TO
MYCOPLASMA PNEUMONIA

Dose per administration 6

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

379 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

	Transdermal	<input type="checkbox"/>
	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 (<i>dd MMM yyyy</i>)	01 OCT 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (<i>dd MMM yyyy</i>)	10 OCT 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication FAMOTIDINE

Prophylaxis Yes
No

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 20

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)

381 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

	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)	01 OCT 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

If not Ongoing, End date (dd MMM yyyy)	10 OCT 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication ALDACTONE
(SPIRONOLACTONE)

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 30

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)

383 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

	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)	30 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

If not Ongoing, End date (dd MMM yyyy)	30 OCT 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="checkbox"/>

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication FUROSEMIDE

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 20

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)

385 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 30 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 30 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication TUSSE-ORGANIDIN DM-S
(DEXTROMETHORPHAN-GUAIF
ENESIN)

Prophylaxis Yes
No

Indication COUGH

Dose per administration 10-100/ 5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify MG/ML

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)

387 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

	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)	30 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

If not Ongoing, End date (dd MMM yyyy)	10 OCT 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="checkbox"/>

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication B1 VITAMIN

Prophylaxis Yes
No

Indication THIAMIN DEFICIENCY

Dose per administration 100

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 30 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 30 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication PROAIR HFA

Prophylaxis Yes
No

Indication SHORTNESS OF BREATH

Dose per administration 90

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

2 PUFFS EVERY 6 HOURS

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

391 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input checked="" type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 30 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 10 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Name of Medication LANTUS SOLOSTAR

Prophylaxis Yes
No

Indication TYPE 2 DIABETES MELLITUS

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

393 of 2601

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 30 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 10 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 04 May 2021 00:28:26

Generated On: 09 Jun 2021 16:14:45

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
30 SEP 2020	ABDOMINAL ULTRASOUND	Adverse Event	
30 SEP 2020	CHEST X-RAY	Adverse Event	
30 SEP 2020	ULTRASOUND OF THE KIDNEYS AND URINARY BLADDER	Adverse Event	
01 OCT 2020	COMPUTED TOMOGRAPHY ANGIOGRAM CHEST WITH IV CONTRAST	Adverse Event	
02 OCT 2020	TRANSTHORACIC ECHOCARDIOGRAM	Adverse Event	
04 OCT 2020	CHEST X-RAY	Adverse Event	
04 OCT 2020	COMPUTED TOMOGRAPHY OF THE ABDOMEN/PELVIS W/O CONTRAST	Adverse Event	
05 OCT 2020	ULTRASOUND PARACENTESIS WITH IMAGE	Adverse Event	
05 OCT 2020	ABDOMINAL X-RAY	Adverse Event	
06 OCT 2020	RIGHT COLON BIOPSY	Adverse Event	
06 OCT 2020	LEFT COLON BIOPSY	Adverse Event	
06 OCT 2020	COLONOSCOPY	Adverse Event	
07 OCT 2020	ABDOMINAL X-RAY	Adverse Event	

US3252516

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:14:45

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify)

SAE (specify)

Complete

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by
participant (specify)

Other

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event

Unknown

Other

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes

No

Unknown

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	14

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	14
Date of submission (Pre-filled from custom function)	13/OCT/2020 10:00
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	14
Date of submission (Pre-filled from custom function)	21/OCT/2020 20:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	14
Date of submission (Pre-filled from custom function)	21/OCT/2020 20:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	14
Date of submission (Pre-filled from custom function)	22/OCT/2020 14:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	14
Date of submission (Pre-filled from custom function)	25/NOV/2020 13:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	14
Date of submission (Pre-filled from custom function)	11/FEB/2021 09:13
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	14
Date of submission (Pre-filled from custom function)	18/FEB/2021 15:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	14
Date of submission (Pre-filled from custom function)	26/FEB/2021 10:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (9)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	14
Date of submission (Pre-filled from custom function)	08/MAR/2021 09:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (10)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	14
Date of submission (Pre-filled from custom function)	13/APR/2021 13:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (11)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	14
Date of submission (Pre-filled from custom function)	19/APR/2021 09:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (12)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	14
Date of submission (Pre-filled from custom function)	22/APR/2021 13:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (13)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	14
Date of submission (Pre-filled from custom function)	23/APR/2021 12:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (14)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	14
Date of submission (Pre-filled from custom function)	26/APR/2021 17:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

SAEID	USA-US108-2021-MRNA-1273-P30 1000020
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

SAEID	USA-US108-2021-MRNA-1273-P301000020
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/APR/2021 10:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

SAEID	USA-US108-2021-MRNA-1273-P301000020
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/APR/2021 12:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 11:45:17

Generated On: 09 Jun 2021 16:14:45

SAEID	USA-US108-2021-MRNA-1273-P301000020
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	23/APR/2021 12:06
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

Audit

US3252516 (Prod: Centex Studies Inc)

US3252516

Form: Participant Creation

Generated On: 09 Jun 2021 16:14:45

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:19:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
User entered 'US3252516'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 16:45:31

US3252516

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:59:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:07:37

US3252516

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:59:58
User entered '21 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 16:45:32

US3252516

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:59:58
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Sep 2020 17:07:37

US3252516

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered 'SCRN'	System	21 Sep 2020 17:07:37

US3252516

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:45

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:00:43
User entered (b) (6) 1980'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 16:45:33

US3252516

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:45

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:00:43
User entered '40'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:45

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered 'YEARS'	System	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:45

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '40'	System	21 Sep 2020 17:11:22

US3252516

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:45

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded. DataPoint Verified.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
	(b) (4), (b) (6)	22 Feb 2021 16:00:43
User entered 'Male (M)'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:45

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:00:43
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:45

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:00:43
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:45

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:00:43
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:45

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:00:43
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:45

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:00:43
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:45

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:00:43
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:00:43
User entered '1'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:45

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:00:43
User entered 'Hispanic'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:45

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:00:43
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:45

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded. DataPoint Verified.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
	(b) (4), (b) (6)	22 Feb 2021 16:00:43
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:45

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:00:24
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 17:11:22

US3252516

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:45

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered 'Sep 2020'	System	21 Sep 2020 17:11:22

US3252516

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:45

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '2020'	System	21 Sep 2020 17:11:22

US3252516

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:45

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:00:24
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	21 Sep 2020 17:11:22

US3252516

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:45

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:00:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:11:22

US3252516

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:45

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:00:24
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:11:22

US3252516

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:45

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:00:24
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:11:22

US3252516

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:45

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:00:24
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 17:11:22

US3252516

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:45

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:00:24
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 16:45:32

US3252516

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:45

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '1'	System	21 Sep 2020 17:11:27

US3252516

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:14:45

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:11:27

US3252516

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:14:45

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:12
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:09:12

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:39
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:10:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:10:49
Data point term sent to Coder	System	22 Sep 2020 05:10:28
User entered 'Type II Diabetes Mellitus'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:39
User entered 'UN UNK 2010'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:39
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:39
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:39
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:45

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:39
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:45

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered 'Jan 2010'	System	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '2010'	System	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered empty.	System	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered empty.	System	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:39
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 05:10:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 05:10:49
Data point term sent to Coder	System	22 Sep 2020 05:10:28
User entered 'Hypertension'	Nancy Torrence (b) (4)	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:39
User entered 'UN UNK 2010'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:39
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:39
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:39
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:45

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:39
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:45

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered 'Jan 2010'	System	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '2010'	System	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered empty.	System	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered empty.	System	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 21:45:44
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User coded data point as SOC: Hepatobiliary disorders, HLG: Hepatic and hepatobiliary disorders, HLT: Hepatic fibrosis and cirrhosis, PT: Cirrhosis alcoholic, LLT: Alcoholic cirrhosis of liver - version MedDRA\23.0.	Coder Import (b) (4)	27 Apr 2021 08:07:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	27 Apr 2021 08:07:58
Data point term sent to Coder	System	27 Apr 2021 06:16:44
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 06:16:43
Coding entries removed.	(b) (4), (b) (6)	27 Apr 2021 06:16:43
Signature has been broken.	(b) (4), (b) (6)	27 Apr 2021 06:16:43
User entered 'alcoholic LIVER CIRRHOSIS' reason for change: New Information	(b) (4), (b) (6)	27 Apr 2021 06:16:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:39
User coded data point as SOC: Hepatobiliary disorders, HLG: Hepatic and hepatobiliary disorders, HLT: Hepatic fibrosis and cirrhosis, PT: Hepatic cirrhosis, LLT: Liver cirrhosis - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 05:11:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 05:11:50
Data point term sent to Coder	System	22 Sep 2020 05:11:29
User entered 'Liver Cirrhosis'	Nancy Torrence (b) (4)	22 Sep 2020 05:11:00
	(b) (4)	

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:39
User entered 'UN UNK 2010'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:11:00

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:39
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:11:00

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:39
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:11:00

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:39
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:11:00

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:39
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:11:00

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered 'Jan 2010'	System	22 Sep 2020 05:11:00

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '2010'	System	22 Sep 2020 05:11:00

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered empty.	System	22 Sep 2020 05:11:00

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered empty.	System	22 Sep 2020 05:11:00

US3252516

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 21:45:44
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	27 Apr 2021 06:18:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Apr 2021 06:18:57
Data point term sent to Coder	System	27 Apr 2021 06:17:47
User entered 'insomnia'	(b) (4), (b) (6)	27 Apr 2021 06:17:08

US3252516

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 21:45:44
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'un Apr 2010'	(b) (4), (b) (6)	27 Apr 2021 06:17:08

US3252516

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 21:45:44
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:17:08

US3252516

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 21:45:44
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Apr 2021 06:17:08

US3252516

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 21:45:44
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:17:08

US3252516

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 21:45:44
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:17:08

US3252516

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered 'Apr 2010'	System	27 Apr 2021 06:17:08

US3252516

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '2010'	System	27 Apr 2021 06:17:08

US3252516

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered empty.	System	27 Apr 2021 06:17:08

US3252516

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered empty.	System	27 Apr 2021 06:17:08

US3252516

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 21:45:44
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User coded data point as SOC: Nervous system disorders, HLG: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Seizure, LLT: Seizure - version MedDRA\23.0.	Coder Import (b) (4)	27 Apr 2021 06:18:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Apr 2021 06:18:57
Data point term sent to Coder	System	27 Apr 2021 06:17:45
User entered 'seizure disorder'	(b) (4), (b) (6)	27 Apr 2021 06:17:32

US3252516

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 21:45:44
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'un UNK 2012'	(b) (4), (b) (6)	27 Apr 2021 06:17:32

US3252516

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 21:45:44
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:17:32

US3252516

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 21:45:44
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Apr 2021 06:17:32

US3252516

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 21:45:44
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:17:32

US3252516

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 21:45:44
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:17:32

US3252516

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:45

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered 'Jan 2012'	System	27 Apr 2021 06:17:32

US3252516

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '2012'	System	27 Apr 2021 06:17:32

US3252516

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered empty.	System	27 Apr 2021 06:17:32

US3252516

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered empty.	System	27 Apr 2021 06:17:32

US3252516

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 21:45:44
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	27 Apr 2021 06:20:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Apr 2021 06:20:15
Data point term sent to Coder	System	27 Apr 2021 06:18:47
User entered 'Gastroesophageal Reflux Disease'	(b) (4), (b) (6)	27 Apr 2021 06:17:54

US3252516

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 21:45:44
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'un UNK 2020'	(b) (4), (b) (6)	27 Apr 2021 06:17:54

US3252516

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:45

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 21:45:44
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:17:54

US3252516

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 21:45:44
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Apr 2021 06:17:54

US3252516

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:45

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 21:45:44
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:17:54

US3252516

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 21:45:44
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:17:54

US3252516

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:45

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered 'Jan 2020'	System	27 Apr 2021 06:17:54

US3252516

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '2020'	System	27 Apr 2021 06:17:54

US3252516

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:45

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered empty.	System	27 Apr 2021 06:17:54

US3252516

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:45

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:40:11
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:24:56
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered empty.	System	27 Apr 2021 06:17:54

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:02:06
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	22 Sep 2020 05:12:00
	(b) (4)	

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:02:06
User entered '21 Sep 2020'	Nancy Torrence (b) (4)	22 Sep 2020 05:12:00
	(b) (4)	

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:01:52
User entered '11:28'	Nancy Torrence (b) (4)	22 Sep 2020 05:12:00
	(b) (4)	

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '21 Sep 2020 11:28'	System	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:02:00
User entered '67' in	Nancy Torrence (b) (4)	22 Sep 2020 05:12:00
DataPoint set to visible.	(b) (4) System	21 Sep 2020 17:11:27

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:02:03
User entered '164' lb	Nancy Torrence (b) (4)	22 Sep 2020 05:12:00
DataPoint set to visible.	(b) (4) System	21 Sep 2020 17:11:27

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '25.73974'	System	22 Sep 2020 05:12:00
DataPoint set to visible.	System	21 Sep 2020 17:11:27

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered 'kg/m2'	System	22 Sep 2020 05:12:00
DataPoint set to visible.	System	21 Sep 2020 17:11:27

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:02:06
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	22 Sep 2020 05:12:00
	(b) (4)	

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:02:06
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:02:06
User entered empty.	Nancy Torrence (b) (4)	22 Sep 2020 05:12:00
	(b) (4)	

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:02:06
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered 'bpm'	System	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:02:06
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	22 Sep 2020 05:12:00
	(b) (4)	

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered 'breaths/min'	System	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:02:06
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered 'mmHg'	System	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:02:06
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered 'mmHg'	System	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:06:47
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	22 Sep 2020 05:12:32
	(b) (4)	

US3252516

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:06:47
User entered '21 Sep 2020'	Nancy Torrence (b) (4)	22 Sep 2020 05:12:32
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:24
User entered 'No (N)'	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:24
User entered 'No (N)'	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:24
User entered 'No (N)'	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:24
User entered 'No (N)'	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:24
User entered 'No (N)'	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:24
User entered 'No (N)'	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:24
User entered 'No (N)'	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:24
User entered 'No (N)'	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:24
User entered 'No (N)'	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:24
User entered 'No (N)'	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

[Educators and Students](#) (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded. DataPoint Verified.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
	(b) (4), (b) (6)	22 Feb 2021 16:07:24
User entered 'No (N)'	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:24
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:24
User entered 'Currently not working.'	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
User entered '0'	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:24
User entered '0'	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded. DataPoint Verified.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
	(b) (4), (b) (6)	22 Feb 2021 16:07:24
User entered '0'	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:24
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:24
User entered '0'	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:24
User entered '1'	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
User entered '0'	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:24
User entered empty.	Nancy Torrence (b) (4)	22 Sep 2020 05:13:25
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:56
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	21 Sep 2020 18:17:32

US3252516

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:56
User entered '21 Sep 2020'	Joanna Gurrola Mahoney (b) (4)	21 Sep 2020 18:17:32

US3252516

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:07:56
User entered 'Clinic (Clinic)'	Joanna Gurrola Mahoney (b) (4)	21 Sep 2020 18:17:32

US3252516

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered 'VISIT1'	System	21 Sep 2020 18:17:32

US3252516

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:45

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:08:17
User entered '21 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 16:50:28

US3252516

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:45

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:08:17
User entered '146657'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 16:50:28

US3252516

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:45

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:08:17
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 16:50:28

US3252516

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:45

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)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:08:17
User entered 'No (N)'	Nancy Torrence (b) (4)	22 Sep 2020 05:14:30
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:45

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)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:08:17
User entered 'No (N)'	Nancy Torrence (b) (4)	22 Sep 2020 05:14:30
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:45

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:08:17
User entered 'No (N)'	Nancy Torrence (b) (4)	22 Sep 2020 05:14:30
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:45

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:08:17
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	22 Sep 2020 05:14:30
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:45

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:08:17
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	22 Sep 2020 05:14:30
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:45

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:08:17
User entered 'No (N)'	Nancy Torrence (b) (4)	22 Sep 2020 05:14:30
DataPoint set to visible.	(b) (4) System	21 Sep 2020 17:11:22

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:08:27
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:08:29
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:08:27
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:08:29
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User accepted default value 'Pre-Dose (PREDOSE)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:09:50
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	22 Sep 2020 05:18:17
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:09:52
User entered '21 Sep 2020'	Nancy Torrence (b) (4)	22 Sep 2020 05:18:17
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:09:55
User entered '11:28'	Nancy Torrence (b) (4)	22 Sep 2020 05:18:17
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered '21 Sep 2020 11:28'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:09:59
User entered '98.3' F	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:01
User entered 'Oral (Oral)'	Nancy Torrence (b) (4)	22 Sep 2020 05:18:17
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:03
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:05
User entered '85'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered 'bpm'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:07
User entered '16'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered 'breaths/min'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:09
User entered '105'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered 'mmHg'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:11
User entered '75'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered 'mmHg'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:08:27
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:08:29
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User accepted default value 'Post-Dose (POSTDOSE)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:12:55
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	22 Sep 2020 05:18:17
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:12:55
User entered '21 Sep 2020'	Nancy Torrence (b) (4)	22 Sep 2020 05:18:17
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:12:55
User entered '13:29'	Nancy Torrence (b) (4)	22 Sep 2020 05:18:17
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered '21 Sep 2020 13:29'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:12:55
User entered '97.8' F	Nancy Torrence (b) (4)	22 Sep 2020 05:18:17
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:12:55
User entered 'Oral (Oral)'	Nancy Torrence (b) (4)	22 Sep 2020 05:18:17
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:12:55
User entered empty.	Nancy Torrence (b) (4)	22 Sep 2020 05:18:17
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:12:55
User entered '120'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered 'bpm'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:12:55
User entered '18'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered 'breaths/min'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:12:55
User entered '103'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered 'mmHg'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:12:55
User entered '69'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered 'mmHg'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:16
User entered 'No (N)'	Nancy Torrence (b) (4)	22 Sep 2020 05:18:37
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:16
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:37

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:27
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:27
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

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)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:27
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:27
User entered '21 Sep 2020'	Joanna Gurrola Mahoney (b) (4)	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:24
User entered '12:59'	Joanna Gurrola Mahoney (b) (4)	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered '21 Sep 2020 12:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:27
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola Mahoney (b) (4)	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:27
User entered 'ONCE'	System	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:42
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:23:48

US3252516

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:42
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 21SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 10:58:34
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 21SEP2020; however, it has not been received by GCL. Please clarify.' answered with 'Samples have been shipped. AWB Number: 917903344847' (Site from DM).	Uche Ehiemua (b) (4) (b) (4)	12 Oct 2020 16:35:50
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 21SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 19:08:00
User entered '21 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:23:48

US3252516

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:42
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Sep 2020 14:29:32
User entered '12:11' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 14:29:32
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 05:23:48
User entered 'UN:UN' (non-conformant).	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:23:48

US3252516

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered '21 Sep 2020 12:11'	System	23 Sep 2020 14:29:32
User entered '21 Sep 2020 UN:UN' (non-conformant).	System	22 Sep 2020 05:23:48

US3252516

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:14:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:53
User entered '21 Sep 2020'	Nancy Torrence (b) (4)	22 Sep 2020 05:24:32
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:24:32

US3252516

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:53
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	22 Sep 2020 05:24:32
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:53
User entered '12:07'	Nancy Torrence (b) (4)	22 Sep 2020 05:24:32
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered '21 Sep 2020 12:07'	System	22 Sep 2020 05:24:32

US3252516

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:24:32

US3252516

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:53
User entered 'No (N)'	Nancy Torrence (b) (4)	22 Sep 2020 05:24:32
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:53
User entered empty.	Nancy Torrence (b) (4)	22 Sep 2020 05:24:32
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered empty.	System	22 Sep 2020 05:24:32

US3252516

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:10:58
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	22 Sep 2020 05:24:37
	(b) (4)	

US3252516

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered '1'	System	22 Sep 2020 05:24:37

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:47:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '2c54fee6-b4aa-42f8-ac47-f336a4bd90d9'	System	21 Sep 2020 18:47:20
User entered 'Yes (Y)'	System	21 Sep 2020 18:47:20

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:47:08', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '2c54fee6-b4aa-42f8-ac47-f336a4bd90d9' User entered '97.8'	System	21 Sep 2020 18:47:20
	System	21 Sep 2020 18:47:20

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:47:12', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '2c54fee6-b4aa-42f8-ac47-f336a4bd90d9'	System	21 Sep 2020 18:47:20
User entered 'No (N)'	System	21 Sep 2020 18:47:20

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:47:17', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '2c54fee6-b4aa-42f8-ac47-f336a4bd90d9' User entered '21 Sep 2020 13:47'	System	21 Sep 2020 18:47:20
	System	21 Sep 2020 18:47:20

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '21 Sep 2020 13:19'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '21 Sep 2020 15:49'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:08:47', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f595ed80-4147-49bb-8e98-38dabe60392f' User entered 'Yes (Y)'	System	22 Sep 2020 00:09:12
	System	22 Sep 2020 00:09:12

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:08:57', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f595ed80-4147-49bb-8e98-38dabe60392f' User entered '98.6'	System	22 Sep 2020 00:09:12
	System	22 Sep 2020 00:09:12

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:02', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f595ed80-4147-49bb-8e98-38dabe60392f' User entered 'No (N)'	System	22 Sep 2020 00:09:12
	System	22 Sep 2020 00:09:12

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:10', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f595ed80-4147-49bb-8e98-38dabe60392f' User entered '21 Sep 2020 19:09'	System	22 Sep 2020 00:09:12
	System	22 Sep 2020 00:09:12

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '21 Sep 2020 16:44'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 2'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:46:57', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '24bdbded-03d4-4615-8d43-f6c9a85cbcd5' User entered 'Yes (Y)'	System	23 Sep 2020 01:47:37
	System	23 Sep 2020 01:47:37

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:47:09', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '24bdbded-03d4-4615-8d43-f6c9a85cbcd5' User entered '97.8'	System	23 Sep 2020 01:47:37
	System	23 Sep 2020 01:47:37

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:47:14', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '24bdbded-03d4-4615-8d43-f6c9a85cbcd5'	System	23 Sep 2020 01:47:37
User entered 'No (N)'	System	23 Sep 2020 01:47:37

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:47:20', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '24bdbded-03d4-4615-8d43-f6c9a85cbcd5' User entered '22 Sep 2020 20:47'	System	23 Sep 2020 01:47:37
	System	23 Sep 2020 01:47:37

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 3'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:40:31', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'd9edef30-c0e9-455f-905e-707603644756' User entered 'Yes (Y)'	System	24 Sep 2020 00:40:53
	System	24 Sep 2020 00:40:53

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:40:40', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'd9edef30-c0e9-455f-905e-707603644756' User entered '98.9'	System	24 Sep 2020 00:40:53
	System	24 Sep 2020 00:40:53

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:40:45', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'd9edef30-c0e9-455f-905e-707603644756'	System	24 Sep 2020 00:40:53
User entered 'No (N)'	System	24 Sep 2020 00:40:53

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:40:49', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'd9edef30-c0e9-455f-905e-707603644756' User entered '23 Sep 2020 19:40'	System	24 Sep 2020 00:40:53
	System	24 Sep 2020 00:40:53

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 4'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:48:31', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '30eecf9b-a96a-40e6-a14b-55fbca6403ea' User entered 'Yes (Y)'	System	25 Sep 2020 00:49:00
	System	25 Sep 2020 00:49:00

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:48:40', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '30eecf9b-a96a-40e6-a14b-55fbca6403ea' User entered '98.1'	System	25 Sep 2020 00:49:00
	System	25 Sep 2020 00:49:00

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:48:44', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '30eecf9b-a96a-40e6-a14b-55fbca6403ea'	System	25 Sep 2020 00:49:00
User entered 'No (N)'	System	25 Sep 2020 00:49:00

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:48:55', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '30eecf9b-a96a-40e6-a14b-55fbca6403ea' User entered '24 Sep 2020 19:48'	System	25 Sep 2020 00:49:00
	System	25 Sep 2020 00:49:00

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 5'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:03:18', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f66b33a8-da8d-4abb-b618-bcfcabfe50ea' User entered 'Yes (Y)'	System	26 Sep 2020 06:03:37
	System	26 Sep 2020 06:03:37

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:03:25', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f66b33a8-da8d-4abb-b618-bcfcabfe50ea' User entered '98.1'	System	26 Sep 2020 06:03:37
	System	26 Sep 2020 06:03:37

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:03:30', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f66b33a8-da8d-4abb-b618-bcfcabfe50ea' User entered 'No (N)'	System	26 Sep 2020 06:03:37
	System	26 Sep 2020 06:03:37

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:03:34', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f66b33a8-da8d-4abb-b618-bcfcabfe50ea' User entered '26 Sep 2020 01:03'	System	26 Sep 2020 06:03:37
	System	26 Sep 2020 06:03:37

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 6'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:33:35', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'bcf48415-38a5-4fd0-9538-3464b7bc4ca5' User entered 'Yes (Y)'	System	26 Sep 2020 20:33:58
	System	26 Sep 2020 20:33:58

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:33:48', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'bcf48415-38a5-4fd0-9538-3464b7bc4ca5' User entered '96.4'	System	26 Sep 2020 20:33:58
	System	26 Sep 2020 20:33:58

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:33:53', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'bcf48415-38a5-4fd0-9538-3464b7bc4ca5'	System	26 Sep 2020 20:33:58
User entered 'No (N)'	System	26 Sep 2020 20:33:58

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:33:55', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'bcf48415-38a5-4fd0-9538-3464b7bc4ca5' User entered '26 Sep 2020 15:33'	System	26 Sep 2020 20:33:58
	System	26 Sep 2020 20:33:58

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 7'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:08', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0b87fbd8-d25e-4702-af2e-5af6dd9215a2'	System	28 Sep 2020 09:07:30
User entered 'Yes (Y)'	System	28 Sep 2020 09:07:30

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:18', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0b87fbd8-d25e-4702-af2e-5af6dd9215a2'	System	28 Sep 2020 09:07:30
User entered '98.3'	System	28 Sep 2020 09:07:30

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:23', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0b87fbd8-d25e-4702-af2e-5af6dd9215a2'	System	28 Sep 2020 09:07:30
User entered 'No (N)'	System	28 Sep 2020 09:07:30

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:26', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0b87fbd8-d25e-4702-af2e-5af6dd9215a2'	System	28 Sep 2020 09:07:30
User entered '28 Sep 2020 04:07'	System	28 Sep 2020 09:07:30

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:47:30', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9da3eb66-4ead-443e-847c-af02b46c6f6d'	System	21 Sep 2020 18:48:05
User entered 'None (1)'	System	21 Sep 2020 18:48:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:47:33', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9da3eb66-4ead-443e-847c-af02b46c6f6d'	System	21 Sep 2020 18:48:05
User entered 'No (N)'	System	21 Sep 2020 18:48:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:47:36', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9da3eb66-4ead-443e-847c-af02b46c6f6d'	System	21 Sep 2020 18:48:05
User entered 'No (N)'	System	21 Sep 2020 18:48:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:47:47', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9da3eb66-4ead-443e-847c-af02b46c6f6d'	System	21 Sep 2020 18:48:05
User entered 'None (1)'	System	21 Sep 2020 18:48:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:48:01', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9da3eb66-4ead-443e-847c-af02b46c6f6d' User entered '21 Sep 2020 13:48'	System	21 Sep 2020 18:48:05
	System	21 Sep 2020 18:48:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '21 Sep 2020 13:19'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '21 Sep 2020 15:49'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:24', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '78953a7a-2141-4a75-b47e-941cad3e05b1' User entered 'None (1)'	System	22 Sep 2020 00:09:45
	System	22 Sep 2020 00:09:45

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:28', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '78953a7a-2141-4a75-b47e-941cad3e05b1' User entered 'No (N)'	System	22 Sep 2020 00:09:45
	System	22 Sep 2020 00:09:45

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:32', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '78953a7a-2141-4a75-b47e-941cad3e05b1' User entered 'No (N)'	System	22 Sep 2020 00:09:45
	System	22 Sep 2020 00:09:45

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:39', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '78953a7a-2141-4a75-b47e-941cad3e05b1' User entered 'None (1)'	System	22 Sep 2020 00:09:45
	System	22 Sep 2020 00:09:45

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:43', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '78953a7a-2141-4a75-b47e-941cad3e05b1' User entered '21 Sep 2020 19:09'	System	22 Sep 2020 00:09:45
	System	22 Sep 2020 00:09:45

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '21 Sep 2020 16:44'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 2'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:47:35', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '4a97ebdd-c25d-4eba-9289-61912db2f4e1' User entered 'None (1)'	System	23 Sep 2020 01:48:13
	System	23 Sep 2020 01:48:13

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:47:39', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '4a97ebdd-c25d-4eba-9289-61912db2f4e1' User entered 'No (N)'	System	23 Sep 2020 01:48:13
	System	23 Sep 2020 01:48:13

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:47:45', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '4a97ebdd-c25d-4eba-9289-61912db2f4e1' User entered 'No (N)'	System	23 Sep 2020 01:48:13
	System	23 Sep 2020 01:48:13

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:47:58', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '4a97ebdd-c25d-4eba-9289-61912db2f4e1' User entered 'None (1)'	System	23 Sep 2020 01:48:13
	System	23 Sep 2020 01:48:13

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:48:06', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '4a97ebdd-c25d-4eba-9289-61912db2f4e1' User entered '22 Sep 2020 20:48'	System	23 Sep 2020 01:48:13
	System	23 Sep 2020 01:48:13

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 3'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:40:56', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7371380d-10d2-48d6-a613-6032cf580cde' User entered 'None (1)'	System	24 Sep 2020 00:41:19
	System	24 Sep 2020 00:41:19

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7371380d-10d2-48d6-a613-6032cf580cde' User entered 'No (N)'	System	24 Sep 2020 00:41:19
	System	24 Sep 2020 00:41:19

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:08', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7371380d-10d2-48d6-a613-6032cf580cde' User entered 'No (N)'	System	24 Sep 2020 00:41:19
	System	24 Sep 2020 00:41:19

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:12', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7371380d-10d2-48d6-a613-6032cf580cde' User entered 'None (1)'	System	24 Sep 2020 00:41:19
	System	24 Sep 2020 00:41:19

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:16', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7371380d-10d2-48d6-a613-6032cf580cde' User entered '23 Sep 2020 19:41'	System	24 Sep 2020 00:41:19
	System	24 Sep 2020 00:41:19

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 4'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:15', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '51ad5560-a9ab-48ce-b2fa-e18db7ac48c1'	System	25 Sep 2020 00:49:36
User entered 'None (1)'	System	25 Sep 2020 00:49:36

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:20', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '51ad5560-a9ab-48ce-b2fa-e18db7ac48c1' User entered 'No (N)'	System	25 Sep 2020 00:49:36
	System	25 Sep 2020 00:49:36

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:23', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '51ad5560-a9ab-48ce-b2fa-e18db7ac48c1'	System	25 Sep 2020 00:49:36
User entered 'No (N)'	System	25 Sep 2020 00:49:36

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:27', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '51ad5560-a9ab-48ce-b2fa-e18db7ac48c1' User entered 'None (1)'	System	25 Sep 2020 00:49:36
	System	25 Sep 2020 00:49:36

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:32', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '51ad5560-a9ab-48ce-b2fa-e18db7ac48c1' User entered '24 Sep 2020 19:49'	System	25 Sep 2020 00:49:36
	System	25 Sep 2020 00:49:36

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 5'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:03:45', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b982bfe5-6a8f-46be-bfd8-719a73f030f0'	System	26 Sep 2020 06:04:05
User entered 'None (1)'	System	26 Sep 2020 06:04:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:03:49', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b982bfe5-6a8f-46be-bfd8-719a73f030f0'	System	26 Sep 2020 06:04:05
User entered 'No (N)'	System	26 Sep 2020 06:04:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:03:53', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b982bfe5-6a8f-46be-bfd8-719a73f030f0'	System	26 Sep 2020 06:04:05
User entered 'No (N)'	System	26 Sep 2020 06:04:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:03:59', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b982bfe5-6a8f-46be-bfd8-719a73f030f0'	System	26 Sep 2020 06:04:05
User entered 'None (1)'	System	26 Sep 2020 06:04:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:04:02', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b982bfe5-6a8f-46be-bfd8-719a73f030f0' User entered '26 Sep 2020 01:04'	System	26 Sep 2020 06:04:05
	System	26 Sep 2020 06:04:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 6'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:45

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:34:09', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'e542fbcf-b3ed-4815-b394-e3cc34b1abcf' User entered 'None (1)'	System	26 Sep 2020 20:34:31
	System	26 Sep 2020 20:34:31

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:34:18', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'e542fbcf-b3ed-4815-b394-e3cc34b1abcf' User entered 'No (N)'	System	26 Sep 2020 20:34:31
	System	26 Sep 2020 20:34:31

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:34:21', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'e542fbcf-b3ed-4815-b394-e3cc34b1abcf' User entered 'No (N)'	System	26 Sep 2020 20:34:31
	System	26 Sep 2020 20:34:31

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:45

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:34:25', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'e542fbcf-b3ed-4815-b394-e3cc34b1abcf' User entered 'None (1)'	System	26 Sep 2020 20:34:31
	System	26 Sep 2020 20:34:31

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:34:29', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'e542fbcf-b3ed-4815-b394-e3cc34b1abcf' User entered '26 Sep 2020 15:34'	System	26 Sep 2020 20:34:31
	System	26 Sep 2020 20:34:31

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 7'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:45

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:33', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'df4a4035-e3f3-48f5-85ce-8285c3e5be5d'	System	28 Sep 2020 09:07:52
User entered 'None (1)'	System	28 Sep 2020 09:07:52

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:37', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'df4a4035-e3f3-48f5-85ce-8285c3e5be5d'	System	28 Sep 2020 09:07:52
User entered 'No (N)'	System	28 Sep 2020 09:07:52

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:41', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'df4a4035-e3f3-48f5-85ce-8285c3e5be5d' User entered 'No (N)'	System	28 Sep 2020 09:07:52
	System	28 Sep 2020 09:07:52

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:45

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:45', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'df4a4035-e3f3-48f5-85ce-8285c3e5be5d'	System	28 Sep 2020 09:07:52
User entered 'None (1)'	System	28 Sep 2020 09:07:52

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:48', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'df4a4035-e3f3-48f5-85ce-8285c3e5be5d' User entered '28 Sep 2020 04:07'	System	28 Sep 2020 09:07:52
	System	28 Sep 2020 09:07:52

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:48:07', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '817048fd-7091-4526-88e7-9195d3c289f0' User entered 'None (0)'	System	21 Sep 2020 18:48:45
	System	21 Sep 2020 18:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:48:17', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '817048fd-7091-4526-88e7-9195d3c289f0' User entered 'None (0)'	System	21 Sep 2020 18:48:45
	System	21 Sep 2020 18:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:48:23', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '817048fd-7091-4526-88e7-9195d3c289f0' User entered 'None (0)'	System	21 Sep 2020 18:48:45
	System	21 Sep 2020 18:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:48:29', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '817048fd-7091-4526-88e7-9195d3c289f0' User entered 'None (0)'	System	21 Sep 2020 18:48:45
	System	21 Sep 2020 18:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:48:32', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '817048fd-7091-4526-88e7-9195d3c289f0' User entered 'None (0)'	System	21 Sep 2020 18:48:45
	System	21 Sep 2020 18:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:48:34', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '817048fd-7091-4526-88e7-9195d3c289f0' User entered 'None (0)'	System	21 Sep 2020 18:48:45
	System	21 Sep 2020 18:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:48:39', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '817048fd-7091-4526-88e7-9195d3c289f0' User entered 'No (N)'	System	21 Sep 2020 18:48:45
	System	21 Sep 2020 18:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:48:42', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '817048fd-7091-4526-88e7-9195d3c289f0' User entered '21 Sep 2020 13:48'	System	21 Sep 2020 18:48:45
	System	21 Sep 2020 18:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '21 Sep 2020 13:19'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '21 Sep 2020 15:49'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:52', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b62f766f-4646-49a0-a8b4-3a2edef7e48c' User entered 'None (0)'	System	22 Sep 2020 00:10:24
	System	22 Sep 2020 00:10:24

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:56', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b62f766f-4646-49a0-a8b4-3a2edef7e48c' User entered 'None (0)'	System	22 Sep 2020 00:10:24
	System	22 Sep 2020 00:10:24

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:59', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b62f766f-4646-49a0-a8b4-3a2edef7e48c' User entered 'None (0)'	System	22 Sep 2020 00:10:24
	System	22 Sep 2020 00:10:24

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:10:05', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b62f766f-4646-49a0-a8b4-3a2edef7e48c' User entered 'None (0)'	System	22 Sep 2020 00:10:24
	System	22 Sep 2020 00:10:24

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:10:09', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b62f766f-4646-49a0-a8b4-3a2edef7e48c' User entered 'None (0)'	System	22 Sep 2020 00:10:24
	System	22 Sep 2020 00:10:24

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:10:12', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b62f766f-4646-49a0-a8b4-3a2edef7e48c' User entered 'None (0)'	System	22 Sep 2020 00:10:24
	System	22 Sep 2020 00:10:24

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:10:18', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b62f766f-4646-49a0-a8b4-3a2edef7e48c' User entered 'No (N)'	System	22 Sep 2020 00:10:24
	System	22 Sep 2020 00:10:24

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:10:21', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b62f766f-4646-49a0-a8b4-3a2edef7e48c' User entered '21 Sep 2020 19:10'	System	22 Sep 2020 00:10:24
	System	22 Sep 2020 00:10:24

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '21 Sep 2020 16:44'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 2'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:48:14', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '84bd47ba-ca00-4a61-a7f0-86c533733253' User entered 'None (0)'	System	23 Sep 2020 01:48:45
	System	23 Sep 2020 01:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:48:17', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '84bd47ba-ca00-4a61-a7f0-86c533733253' User entered 'None (0)'	System	23 Sep 2020 01:48:45
	System	23 Sep 2020 01:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:48:20', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '84bd47ba-ca00-4a61-a7f0-86c533733253' User entered 'None (0)'	System	23 Sep 2020 01:48:45
	System	23 Sep 2020 01:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:48:24', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '84bd47ba-ca00-4a61-a7f0-86c533733253' User entered 'None (0)'	System	23 Sep 2020 01:48:45
	System	23 Sep 2020 01:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:48:27', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '84bd47ba-ca00-4a61-a7f0-86c533733253' User entered 'None (0)'	System	23 Sep 2020 01:48:45
	System	23 Sep 2020 01:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:48:29', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '84bd47ba-ca00-4a61-a7f0-86c533733253' User entered 'None (0)'	System	23 Sep 2020 01:48:45
	System	23 Sep 2020 01:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:48:33', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '84bd47ba-ca00-4a61-a7f0-86c533733253' User entered 'No (N)'	System	23 Sep 2020 01:48:45
	System	23 Sep 2020 01:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:48:37', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '84bd47ba-ca00-4a61-a7f0-86c533733253' User entered '22 Sep 2020 20:48'	System	23 Sep 2020 01:48:45
	System	23 Sep 2020 01:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 3'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:22', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0a63cd3e-45d4-45a0-a567-ba017c8b5b8b' User entered 'None (0)'	System	24 Sep 2020 00:41:55
	System	24 Sep 2020 00:41:55

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:25', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0a63cd3e-45d4-45a0-a567-ba017c8b5b8b' User entered 'None (0)'	System	24 Sep 2020 00:41:55
	System	24 Sep 2020 00:41:55

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:28', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0a63cd3e-45d4-45a0-a567-ba017c8b5b8b' User entered 'None (0)'	System	24 Sep 2020 00:41:55
	System	24 Sep 2020 00:41:55

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:32', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0a63cd3e-45d4-45a0-a567-ba017c8b5b8b' User entered 'None (0)'	System	24 Sep 2020 00:41:55
	System	24 Sep 2020 00:41:55

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:35', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0a63cd3e-45d4-45a0-a567-ba017c8b5b8b' User entered 'None (0)'	System	24 Sep 2020 00:41:55
	System	24 Sep 2020 00:41:55

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:42', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0a63cd3e-45d4-45a0-a567-ba017c8b5b8b' User entered 'None (0)'	System	24 Sep 2020 00:41:55
	System	24 Sep 2020 00:41:55

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:49', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0a63cd3e-45d4-45a0-a567-ba017c8b5b8b' User entered 'No (N)'	System	24 Sep 2020 00:41:55
	System	24 Sep 2020 00:41:55

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:52', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0a63cd3e-45d4-45a0-a567-ba017c8b5b8b' User entered '23 Sep 2020 19:41'	System	24 Sep 2020 00:41:55
	System	24 Sep 2020 00:41:55

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 4'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:39', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'ae1409b2-38ef-4e35-8710-30d2fa833aa6' User entered 'None (0)'	System	25 Sep 2020 00:50:18
	System	25 Sep 2020 00:50:18

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:42', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'ae1409b2-38ef-4e35-8710-30d2fa833aa6'	System	25 Sep 2020 00:50:18
User entered 'None (0)'	System	25 Sep 2020 00:50:18

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:50', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'ae1409b2-38ef-4e35-8710-30d2fa833aa6'	System	25 Sep 2020 00:50:18
User entered 'None (0)'	System	25 Sep 2020 00:50:18

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:54', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'ae1409b2-38ef-4e35-8710-30d2fa833aa6'	System	25 Sep 2020 00:50:18
User entered 'None (0)'	System	25 Sep 2020 00:50:18

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:57', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'ae1409b2-38ef-4e35-8710-30d2fa833aa6'	System	25 Sep 2020 00:50:18
User entered 'None (0)'	System	25 Sep 2020 00:50:18

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:50:06', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'ae1409b2-38ef-4e35-8710-30d2fa833aa6'	System	25 Sep 2020 00:50:18
User entered 'None (0)'	System	25 Sep 2020 00:50:18

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:50:12', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'ae1409b2-38ef-4e35-8710-30d2fa833aa6'	System	25 Sep 2020 00:50:18
User entered 'No (N)'	System	25 Sep 2020 00:50:18

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:50:14', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'ae1409b2-38ef-4e35-8710-30d2fa833aa6' User entered '24 Sep 2020 19:50'	System	25 Sep 2020 00:50:18
	System	25 Sep 2020 00:50:18

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 5'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:04:09', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '5e7d0b86-059e-48fa-a4e3-03b67c73055d' User entered 'None (0)'	System	26 Sep 2020 06:04:39
	System	26 Sep 2020 06:04:39

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:04:12', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '5e7d0b86-059e-48fa-a4e3-03b67c73055d' User entered 'None (0)'	System	26 Sep 2020 06:04:39
	System	26 Sep 2020 06:04:39

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:04:16', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '5e7d0b86-059e-48fa-a4e3-03b67c73055d' User entered 'None (0)'	System	26 Sep 2020 06:04:39
	System	26 Sep 2020 06:04:39

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:04:20', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '5e7d0b86-059e-48fa-a4e3-03b67c73055d' User entered 'None (0)'	System	26 Sep 2020 06:04:39
	System	26 Sep 2020 06:04:39

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:04:24', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '5e7d0b86-059e-48fa-a4e3-03b67c73055d' User entered 'None (0)'	System	26 Sep 2020 06:04:39
	System	26 Sep 2020 06:04:39

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:04:27', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '5e7d0b86-059e-48fa-a4e3-03b67c73055d' User entered 'None (0)'	System	26 Sep 2020 06:04:39
	System	26 Sep 2020 06:04:39

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:04:32', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '5e7d0b86-059e-48fa-a4e3-03b67c73055d' User entered 'No (N)'	System	26 Sep 2020 06:04:39
	System	26 Sep 2020 06:04:39

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:04:36', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '5e7d0b86-059e-48fa-a4e3-03b67c73055d' User entered '26 Sep 2020 01:04'	System	26 Sep 2020 06:04:39
	System	26 Sep 2020 06:04:39

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 6'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:34:37', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc527ad4-758f-4680-9bfd-1e50563f2f5d' User entered 'None (0)'	System	26 Sep 2020 20:35:20
	System	26 Sep 2020 20:35:20

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:34:44', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc527ad4-758f-4680-9bfd-1e50563f2f5d'	System	26 Sep 2020 20:35:20
User entered 'None (0)'	System	26 Sep 2020 20:35:20

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:34:49', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc527ad4-758f-4680-9bfd-1e50563f2f5d' User entered 'None (0)'	System	26 Sep 2020 20:35:20
	System	26 Sep 2020 20:35:20

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:34:55', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc527ad4-758f-4680-9bfd-1e50563f2f5d' User entered 'None (0)'	System	26 Sep 2020 20:35:20
	System	26 Sep 2020 20:35:20

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:35:05', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc527ad4-758f-4680-9bfd-1e50563f2f5d' User entered 'None (0)'	System	26 Sep 2020 20:35:20
	System	26 Sep 2020 20:35:20

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:35:08', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc527ad4-758f-4680-9bfd-1e50563f2f5d' User entered 'None (0)'	System	26 Sep 2020 20:35:20
	System	26 Sep 2020 20:35:20

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:35:13', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc527ad4-758f-4680-9bfd-1e50563f2f5d'	System	26 Sep 2020 20:35:20
User entered 'No (N)'	System	26 Sep 2020 20:35:20

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:35:18', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc527ad4-758f-4680-9bfd-1e50563f2f5d'	System	26 Sep 2020 20:35:20
User entered '26 Sep 2020 15:35'	System	26 Sep 2020 20:35:20

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 7'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:54', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'eb4b1604-6b4f-4401-8f18-c7a18a5346c3' User entered 'None (0)'	System	28 Sep 2020 09:08:27
	System	28 Sep 2020 09:08:27

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:57', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'eb4b1604-6b4f-4401-8f18-c7a18a5346c3' User entered 'None (0)'	System	28 Sep 2020 09:08:27
	System	28 Sep 2020 09:08:27

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:08:03', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'eb4b1604-6b4f-4401-8f18-c7a18a5346c3' User entered 'None (0)'	System	28 Sep 2020 09:08:27
	System	28 Sep 2020 09:08:27

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:08:06', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'eb4b1604-6b4f-4401-8f18-c7a18a5346c3' User entered 'None (0)'	System	28 Sep 2020 09:08:27
	System	28 Sep 2020 09:08:27

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:08:10', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'eb4b1604-6b4f-4401-8f18-c7a18a5346c3' User entered 'None (0)'	System	28 Sep 2020 09:08:27
	System	28 Sep 2020 09:08:27

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:08:12', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'eb4b1604-6b4f-4401-8f18-c7a18a5346c3' User entered 'None (0)'	System	28 Sep 2020 09:08:27
	System	28 Sep 2020 09:08:27

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:08:21', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'eb4b1604-6b4f-4401-8f18-c7a18a5346c3' User entered 'No (N)'	System	28 Sep 2020 09:08:27
	System	28 Sep 2020 09:08:27

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:08:25', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'eb4b1604-6b4f-4401-8f18-c7a18a5346c3' User entered '28 Sep 2020 04:08'	System	28 Sep 2020 09:08:27
	System	28 Sep 2020 09:08:27

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:54:10
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	06 Oct 2020 02:44:37

US3252516

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:54:10
User entered '28 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	06 Oct 2020 02:44:37

US3252516

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:54:10
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	06 Oct 2020 02:44:37

US3252516

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:54:10
User entered empty.	Nancy Torrence (b) (4) (b) (4)	06 Oct 2020 02:44:37

US3252516

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:54:44
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	06 Oct 2020 02:44:43

US3252516

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered '1'	System	06 Oct 2020 02:44:43

US3252516

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:12:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 14:37:55

US3252516

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:12:15
User entered '05 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 14:37:55

US3252516

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:12:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Oct 2020 14:37:55

US3252516

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:12:15
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:37:55

US3252516

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:13:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 14:38:01

US3252516

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:21:35
User entered 'I'	System	06 Oct 2020 14:38:01

US3252516

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:59
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:21:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 18:54:46

US3252516

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:59
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:21:28
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 18:54:46

US3252516

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:59
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:21:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Oct 2020 18:54:46

US3252516

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:59
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:21:28
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	17 Nov 2020 05:22:37
User entered 'During D22 Safety Phone Call on 12-OCT-2020 Mr. (b) (6) reported a recent hospitalization. He reports being diagnosed with Colitis on 30-SEP-2020 and was hospitalized for a total of nine days. Patient was reportedly discharged from Valley Regional Medical Center on 08-OCT-2020 and was given a prescription for Metronidazole 500 mg TID and Levofloxacin 500 mg once a day. Patient started both of these medications yesterday on 11-OCT-2020. Patient was sent a medical release form via email in order to obtain records from his hospitalization. Will continue to update information as it becomes available.' (non-conformant).	(b) (4), (b) (6)	12 Oct 2020 18:54:46

US3252516

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:59
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:21:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 18:54:54

US3252516

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:59
User entered 'I'	System	12 Oct 2020 18:54:54

US3252516

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:13:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:53:04

US3252516

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:13:57
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 16:53:04

US3252516

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[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 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:13:57
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Oct 2020 16:53:04

US3252516

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered 'VISIT2'	System	20 Oct 2020 16:53:04

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User accepted default value 'Pre-Dose (PREDOSE)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:14:17
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:14:19
User entered '20 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:14:10
User entered '11:19'	Nancy Torrence (b) (4)	21 Oct 2020 11:01:34
	(b) (4)	

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered '20 Oct 2020 11:19'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:14:13
User entered '98.5' F	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:14:16
User entered 'Oral (Oral)'	Nancy Torrence (b) (4)	21 Oct 2020 11:01:34
	(b) (4)	

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:14:23
User entered empty.	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:14:26
User entered '84'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered 'bpm'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:14:28
User entered '16'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered 'breaths/min'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:14:30
User entered '94'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered 'mmHg'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:14:32
User entered '60'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered 'mmHg'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User accepted default value 'Post-Dose (POSTDOSE)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:14:47
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:14:49
User entered '20 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:14:53
User entered '12:21'	Nancy Torrence (b) (4)	21 Oct 2020 11:01:34
	(b) (4)	

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered '20 Oct 2020 12:21'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:14:56
User entered '98.1' F	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:14:58
User entered 'Oral (Oral)'	Nancy Torrence (b) (4)	21 Oct 2020 11:01:34
	(b) (4)	

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:15:00
User entered empty.	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:15:05
User entered '70'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered 'bpm'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:15:07
User entered '16'	Nancy Torrence (b) (4)	21 Oct 2020 11:01:34
	(b) (4)	

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered 'breaths/min'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:15:11
User entered '98'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered 'mmHg'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:15:13
User entered '65'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered 'mmHg'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:15:25
User entered 'No (N)'	Nancy Torrence (b) (4)	21 Oct 2020 11:01:58
	(b) (4)	

US3252516

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:15:25
User entered empty.	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:58

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:15:49
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:15:49
User entered empty.	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

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 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:15:49
User entered empty.	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered 'MRNA-1273 OR PLACEBO'	System	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:15:49
User entered '20 Oct 2020'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:15:49
User entered '11:51'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered '20 Oct 2020 11:51'	System	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:15:49
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola Mahoney (b) (4)	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:15:49
User entered 'ONCE'	System	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered 'INTRAMUSCULAR'	System	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:15:58
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:02:42

US3252516

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:15:58
User entered '20 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:02:42

US3252516

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:15:58
User entered '11:43'	Nancy Torrence (b) (4)	21 Oct 2020 11:02:42
	(b) (4)	

US3252516

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered '20 Oct 2020 11:43'	System	21 Oct 2020 11:02:42

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:14:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:16:20
User entered '20 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:03:06

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:03:06

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:16:20
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:03:06

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:16:20
User entered '11:24'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:03:06

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered '20 Oct 2020 11:24'	System	21 Oct 2020 11:03:06

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:03:06

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:16:20
User entered 'No (N)'	Nancy Torrence (b) (4)	21 Oct 2020 11:03:06
	(b) (4)	

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:16:20
User entered empty.	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:03:06

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered empty.	System	21 Oct 2020 11:03:06

US3252516

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:16:25
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	21 Oct 2020 11:03:18
	(b) (4)	

US3252516

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered '1'	System	21 Oct 2020 11:03:18

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '20 Oct 2020 12:11'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '20 Oct 2020 14:41'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '20 Oct 2020 15:36'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 2'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-22T11:39:25', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7482b55f-03c3-4d07-a38e-9ef6317c7990'	System	22 Oct 2020 16:39:53
User entered 'Yes (Y)'	System	22 Oct 2020 16:39:53

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-22T11:39:38', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7482b55f-03c3-4d07-a38e-9ef6317c7990' User entered '98.5'	System	22 Oct 2020 16:39:53
	System	22 Oct 2020 16:39:53

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-22T11:39:43', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7482b55f-03c3-4d07-a38e-9ef6317c7990'	System	22 Oct 2020 16:39:53
User entered 'No (N)'	System	22 Oct 2020 16:39:53

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-22T11:39:48', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7482b55f-03c3-4d07-a38e-9ef6317c7990' User entered '22 Oct 2020 11:39'	System	22 Oct 2020 16:39:53
	System	22 Oct 2020 16:39:53

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 3'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-23T09:57:59', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'de058327-4c95-4e64-8416-a9409063167d' User entered 'Yes (Y)'	System	23 Oct 2020 14:58:17
	System	23 Oct 2020 14:58:17

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-23T09:58:05', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'de058327-4c95-4e64-8416-a9409063167d' User entered '98.7'	System	23 Oct 2020 14:58:17
	System	23 Oct 2020 14:58:17

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-23T09:58:09', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'de058327-4c95-4e64-8416-a9409063167d' User entered 'No (N)'	System	23 Oct 2020 14:58:17
	System	23 Oct 2020 14:58:17

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-23T09:58:12', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'de058327-4c95-4e64-8416-a9409063167d' User entered '23 Oct 2020 09:58'	System	23 Oct 2020 14:58:17
	System	23 Oct 2020 14:58:17

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 4'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:45

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '23 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '24 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 5'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-25T07:36:37', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7e4076d4-77be-4ab0-adb2-2d5f0f636695' User entered 'Yes (Y)'	System	25 Oct 2020 12:36:57
	System	25 Oct 2020 12:36:57

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-25T07:36:47', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7e4076d4-77be-4ab0-adb2-2d5f0f636695' User entered '98.3'	System	25 Oct 2020 12:36:57
	System	25 Oct 2020 12:36:57

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-25T07:36:51', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7e4076d4-77be-4ab0-adb2-2d5f0f636695'	System	25 Oct 2020 12:36:57
User entered 'No (N)'	System	25 Oct 2020 12:36:57

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-25T07:36:55', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7e4076d4-77be-4ab0-adb2-2d5f0f636695' User entered '25 Oct 2020 07:36'	System	25 Oct 2020 12:36:57
	System	25 Oct 2020 12:36:57

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '24 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '25 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 6'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'e548a52e-799d-4255-b849-1b477587e896'	System	26 Oct 2020 14:46:23
User entered 'Yes (Y)'	System	26 Oct 2020 14:46:23

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:10', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'e548a52e-799d-4255-b849-1b477587e896' User entered '98.7'	System	26 Oct 2020 14:46:23
	System	26 Oct 2020 14:46:23

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:15', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'e548a52e-799d-4255-b849-1b477587e896'	System	26 Oct 2020 14:46:23
User entered 'No (N)'	System	26 Oct 2020 14:46:23

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:20', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'e548a52e-799d-4255-b849-1b477587e896'	System	26 Oct 2020 14:46:23
User entered '26 Oct 2020 09:46'	System	26 Oct 2020 14:46:23

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '25 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '26 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 7'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:04:55', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '624eb070-236c-4e44-8566-9f476bc59928' User entered 'Yes (Y)'	System	27 Oct 2020 13:05:13
	System	27 Oct 2020 13:05:13

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:04', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '624eb070-236c-4e44-8566-9f476bc59928' User entered '98.4'	System	27 Oct 2020 13:05:13
	System	27 Oct 2020 13:05:13

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:45

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:08', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '624eb070-236c-4e44-8566-9f476bc59928' User entered 'No (N)'	System	27 Oct 2020 13:05:13
	System	27 Oct 2020 13:05:13

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:10', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '624eb070-236c-4e44-8566-9f476bc59928' User entered '27 Oct 2020 08:05'	System	27 Oct 2020 13:05:13
	System	27 Oct 2020 13:05:13

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '26 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '27 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '20 Oct 2020 12:11'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '20 Oct 2020 14:41'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '20 Oct 2020 15:36'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 2'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 3'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 4'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '23 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '24 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 5'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '24 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '25 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 6'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:45

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:35', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc7f0bb8-9a3a-460f-aa87-b3c5e37824c4'	System	26 Oct 2020 14:46:53
User entered 'None (1)'	System	26 Oct 2020 14:46:53

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:38', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc7f0bb8-9a3a-460f-aa87-b3c5e37824c4'	System	26 Oct 2020 14:46:53
User entered 'No (N)'	System	26 Oct 2020 14:46:53

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:42', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc7f0bb8-9a3a-460f-aa87-b3c5e37824c4'	System	26 Oct 2020 14:46:53
User entered 'No (N)'	System	26 Oct 2020 14:46:53

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:45

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:48', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc7f0bb8-9a3a-460f-aa87-b3c5e37824c4'	System	26 Oct 2020 14:46:53
User entered 'None (1)'	System	26 Oct 2020 14:46:53

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:50', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc7f0bb8-9a3a-460f-aa87-b3c5e37824c4' User entered '26 Oct 2020 09:46'	System	26 Oct 2020 14:46:53
	System	26 Oct 2020 14:46:53

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '25 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '26 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 7'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:45

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:04:21', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'a7fdf4e9-153d-425d-b832-8f9e45223200'	System	27 Oct 2020 13:04:42
User entered 'None (1)'	System	27 Oct 2020 13:04:42

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:45

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:04:24', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'a7fdf4e9-153d-425d-b832-8f9e45223200'	System	27 Oct 2020 13:04:42
User entered 'No (N)'	System	27 Oct 2020 13:04:42

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:45

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:04:28', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'a7fdf4e9-153d-425d-b832-8f9e45223200'	System	27 Oct 2020 13:04:42
User entered 'No (N)'	System	27 Oct 2020 13:04:42

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:45

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:04:34', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'a7fdf4e9-153d-425d-b832-8f9e45223200'	System	27 Oct 2020 13:04:42
User entered 'None (1)'	System	27 Oct 2020 13:04:42

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:04:40', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'a7fdf4e9-153d-425d-b832-8f9e45223200' User entered '27 Oct 2020 08:04'	System	27 Oct 2020 13:04:42
	System	27 Oct 2020 13:04:42

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '26 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '27 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '20 Oct 2020 12:11'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '20 Oct 2020 14:41'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '20 Oct 2020 15:36'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 2'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 3'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 4'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '23 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '24 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 5'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '24 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '25 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 6'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:56', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9a146ec8-6477-4eb7-96e5-b45eb223bdc2' User entered 'None (0)'	System	26 Oct 2020 14:47:39
	System	26 Oct 2020 14:47:39

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:59', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9a146ec8-6477-4eb7-96e5-b45eb223bdc2' User entered 'None (0)'	System	26 Oct 2020 14:47:39
	System	26 Oct 2020 14:47:39

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:47:03', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9a146ec8-6477-4eb7-96e5-b45eb223bdc2' User entered 'None (0)'	System	26 Oct 2020 14:47:39
	System	26 Oct 2020 14:47:39

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:47:07', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9a146ec8-6477-4eb7-96e5-b45eb223bdc2' User entered 'None (0)'	System	26 Oct 2020 14:47:39
	System	26 Oct 2020 14:47:39

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:47:10', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9a146ec8-6477-4eb7-96e5-b45eb223bdc2' User entered 'None (0)'	System	26 Oct 2020 14:47:39
	System	26 Oct 2020 14:47:39

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:47:13', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9a146ec8-6477-4eb7-96e5-b45eb223bdc2' User entered 'None (0)'	System	26 Oct 2020 14:47:39
	System	26 Oct 2020 14:47:39

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:47:30', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9a146ec8-6477-4eb7-96e5-b45eb223bdc2' User entered 'Yes (Y)'	System	26 Oct 2020 14:47:39
	System	26 Oct 2020 14:47:39

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:47:35', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9a146ec8-6477-4eb7-96e5-b45eb223bdc2' User entered '26 Oct 2020 09:47'	System	26 Oct 2020 14:47:39
	System	26 Oct 2020 14:47:39

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '25 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '26 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 7'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:15', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f05fc127-3a64-4aba-b032-685d5b7658ca' User entered 'None (0)'	System	27 Oct 2020 13:06:01
	System	27 Oct 2020 13:06:01

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:19', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f05fc127-3a64-4aba-b032-685d5b7658ca' User entered 'None (0)'	System	27 Oct 2020 13:06:01
	System	27 Oct 2020 13:06:01

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:54', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f05fc127-3a64-4aba-b032-685d5b7658ca' User entered 'None (0)'	System	27 Oct 2020 13:06:01
	System	27 Oct 2020 13:06:01

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:25', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f05fc127-3a64-4aba-b032-685d5b7658ca' User entered 'None (0)'	System	27 Oct 2020 13:06:01
	System	27 Oct 2020 13:06:01

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:29', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f05fc127-3a64-4aba-b032-685d5b7658ca' User entered 'None (0)'	System	27 Oct 2020 13:06:01
	System	27 Oct 2020 13:06:01

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:32', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f05fc127-3a64-4aba-b032-685d5b7658ca' User entered 'None (0)'	System	27 Oct 2020 13:06:01
	System	27 Oct 2020 13:06:01

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

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)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:39', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f05fc127-3a64-4aba-b032-685d5b7658ca' User entered 'No (N)'	System	27 Oct 2020 13:06:01
	System	27 Oct 2020 13:06:01

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:58', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f05fc127-3a64-4aba-b032-685d5b7658ca' User entered '27 Oct 2020 08:05'	System	27 Oct 2020 13:06:01
	System	27 Oct 2020 13:06:01

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '26 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:35
User entered '27 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:24:57
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	28 Oct 2020 05:13:43

US3252516

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:24:57
User entered '27 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	28 Oct 2020 05:13:43

US3252516

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:24:57
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	28 Oct 2020 05:13:43

US3252516

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:24:57
User entered empty.	Nancy Torrence (b) (4) (b) (4)	28 Oct 2020 05:13:43

US3252516

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:25:04
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	28 Oct 2020 05:13:50

US3252516

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered '1'	System	28 Oct 2020 05:13:50

US3252516

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:29:01
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 02:42:46

US3252516

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:29:01
User entered '3 Nov 2020'	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 02:42:46

US3252516

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:29:01
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 02:42:46

US3252516

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:29:01
User entered empty.	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 02:42:46

US3252516

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:29:06
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	04 Nov 2020 02:42:50
	(b) (4)	

US3252516

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered 'I'	System	04 Nov 2020 02:42:50

US3252516

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:30:20
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	10 Nov 2020 20:04:39

US3252516

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:30:20
User entered '10 Nov 2020'	Nancy Torrence (b) (4)	10 Nov 2020 20:04:39
	(b) (4)	

US3252516

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:30:20
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	10 Nov 2020 20:04:39

US3252516

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:30:20
User entered empty.	Nancy Torrence (b) (4) (b) (4)	10 Nov 2020 20:04:39

US3252516

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:30:41
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	10 Nov 2020 20:04:46

US3252516

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered '1'	System	10 Nov 2020 20:04:46

US3252516

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:00
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Nov 2020 09:39:33
	(b) (4)	

US3252516

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:00
User entered '17 Nov 2020'	Shannon Moyer (b) (4)	18 Nov 2020 09:39:33
	(b) (4)	

US3252516

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[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 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:00
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4)	18 Nov 2020 09:39:33
	(b) (4)	

US3252516

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered 'VISIT3'	System	18 Nov 2020 09:39:33

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:30
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Nov 2020 09:40:27
	(b) (4)	

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:30
User entered '17 Nov 2020'	Shannon Moyer (b) (4)	18 Nov 2020 09:40:27
	(b) (4)	

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:30
User entered '10:31'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered '17 Nov 2020 10:31'	System	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:30
User entered '98.3' F	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:30
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	18 Nov 2020 09:40:27
	(b) (4)	

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:30
User entered empty.	Shannon Moyer (b) (4)	18 Nov 2020 09:40:27
	(b) (4)	

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:30
User entered '82'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered 'bpm'	System	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:30
User entered '15'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered 'breaths/min'	System	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:30
User entered '112'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered 'mmHg'	System	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:30
User entered '74'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered 'mmHg'	System	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05

US3252516

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:36
User entered 'No (N)'	Shannon Moyer (b) (4)	18 Nov 2020 09:40:34
	(b) (4)	

US3252516

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:36
User entered empty.	Shannon Moyer (b) (4)	18 Nov 2020 09:40:34
	(b) (4)	

US3252516

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:43
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Nov 2020 09:40:48
	(b) (4)	

US3252516

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:43
User entered '17 Nov 2020'	Shannon Moyer (b) (4)	18 Nov 2020 09:40:48
	(b) (4)	

US3252516

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:43
User entered '10:53'	Shannon Moyer (b) (4)	18 Nov 2020 09:40:48
	(b) (4)	

US3252516

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered '17 Nov 2020 10:53'	System	18 Nov 2020 09:40:48

US3252516

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:09:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:47
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	18 Nov 2020 09:40:55
	(b) (4)	

US3252516

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered '1'	System	18 Nov 2020 09:40:55

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-11-22T16:23:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '43d42283-155a-4412-bd26-964ba137a3a3'	System	22 Nov 2020 22:23:14
User entered 'No (N)'	System	22 Nov 2020 22:23:14

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-11-22T16:23:07', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '43d42283-155a-4412-bd26-964ba137a3a3'	System	22 Nov 2020 22:23:14
User entered 'No (N)'	System	22 Nov 2020 22:23:14

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-11-22T16:23:12', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '43d42283-155a-4412-bd26-964ba137a3a3'	System	22 Nov 2020 22:23:14
User entered '22 Nov 2020 16:23:12'	System	22 Nov 2020 22:23:14

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-11-25T10:58:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'bc602664-91c8-422c-8bd2-6b7d72ea1320'	System	25 Nov 2020 16:58:36
User entered 'No (N)'	System	25 Nov 2020 16:58:36

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-11-25T10:58:04', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'bc602664-91c8-422c-8bd2-6b7d72ea1320'	System	25 Nov 2020 16:58:36
User entered 'No (N)'	System	25 Nov 2020 16:58:36

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-11-25T10:58:32', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'bc602664-91c8-422c-8bd2-6b7d72ea1320'	System	25 Nov 2020 16:58:36
User entered '25 Nov 2020 10:58:32'	System	25 Nov 2020 16:58:36

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-12-02T11:53:59', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'aefa0b22-2812-41ed-a941-dc299aad6fce'	System	02 Dec 2020 17:54:08
User entered 'No (N)'	System	02 Dec 2020 17:54:08

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-12-02T11:53:53', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'aefa0b22-2812-41ed-a941-dc299aad6fce'	System	02 Dec 2020 17:54:08
User entered 'No (N)'	System	02 Dec 2020 17:54:08

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-12-02T11:54:05', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'aefa0b22-2812-41ed-a941-dc299aad6fce' User entered '02 Dec 2020 11:54:05'	System	02 Dec 2020 17:54:08
	System	02 Dec 2020 17:54:08

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-12-09T12:00:51', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '88d9feb0-e2d9-410f-8c9f-dfedc11a2c5a'	System	09 Dec 2020 18:01:02
User entered 'No (N)'	System	09 Dec 2020 18:01:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-12-09T12:00:53', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '88d9feb0-e2d9-410f-8c9f-dfedc11a2c5a'	System	09 Dec 2020 18:01:02
User entered 'No (N)'	System	09 Dec 2020 18:01:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-12-09T12:00:56', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '88d9feb0-e2d9-410f-8c9f-dfedc11a2c5a' User entered '09 Dec 2020 12:00:56'	System	09 Dec 2020 18:01:02
	System	09 Dec 2020 18:01:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-12-17T19:26:56', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '55fffc84-d944-4e9b-b56b-6ee4659e3f9f'	System	18 Dec 2020 01:27:08
User entered 'No (N)'	System	18 Dec 2020 01:27:08

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-12-17T19:27:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '55fffc84-d944-4e9b-b56b-6ee4659e3f9f' User entered 'No (N)'	System	18 Dec 2020 01:27:08
	System	18 Dec 2020 01:27:08

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-12-17T19:27:04', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '55fffc84-d944-4e9b-b56b-6ee4659e3f9f' User entered '17 Dec 2020 19:27:04'	System	18 Dec 2020 01:27:08
	System	18 Dec 2020 01:27:08

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-12-31T19:09:18', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '6026bdda-e2f0-47e8-8721-ad42b309c706'	System	01 Jan 2021 01:09:34
User entered 'No (N)'	System	01 Jan 2021 01:09:34

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-12-31T19:09:23', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '6026bdda-e2f0-47e8-8721-ad42b309c706'	System	01 Jan 2021 01:09:34
User entered 'No (N)'	System	01 Jan 2021 01:09:34

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-12-31T19:09:29', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '6026bdda-e2f0-47e8-8721-ad42b309c706' User entered '31 Dec 2020 19:09:29'	System	01 Jan 2021 01:09:34
	System	01 Jan 2021 01:09:34

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-01-23T19:20:56', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '6b82e411-a056-43f8-9654-5f466d48efda' User entered 'No (N)'	System	24 Jan 2021 01:21:14
	System	24 Jan 2021 01:21:14

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-01-23T19:21:03', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '6b82e411-a056-43f8-9654-5f466d48efda'	System	24 Jan 2021 01:21:14
User entered 'No (N)'	System	24 Jan 2021 01:21:14

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-01-23T19:21:11', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '6b82e411-a056-43f8-9654-5f466d48efda' User entered '23 Jan 2021 19:21:11'	System	24 Jan 2021 01:21:14
	System	24 Jan 2021 01:21:14

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-03-12T00:07:00-06:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'ef70213c-b6b4-4736-863c-8c0d90976bbc' User entered 'No (N)'	System	12 Mar 2021 06:07:25
	System	12 Mar 2021 06:07:25

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-03-12T00:07:08-06:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'ef70213c-b6b4-4736-863c-8c0d90976bbc' User entered 'No (N)'	System	12 Mar 2021 06:07:25
	System	12 Mar 2021 06:07:25

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-03-12T00:07:20-06:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'ef70213c-b6b4-4736-863c-8c0d90976bbc' User entered '12 Mar 2021 00:07:20'	System	12 Mar 2021 06:07:25
	System	12 Mar 2021 06:07:25

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-03-19T11:01:43-05:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dacc0d23-2803-4ca9-b3b9-9c4d8206e380'	System	19 Mar 2021 16:09:39
User entered 'Yes (Y)'	System	19 Mar 2021 16:09:39

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-03-19T11:02:07-05:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dacc0d23-2803-4ca9-b3b9-9c4d8206e380'	System	19 Mar 2021 16:09:39
User entered 'Yes (Y)'	System	19 Mar 2021 16:09:39

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please 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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-03-19T11:02:11-05:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dacc0d23-2803-4ca9-b3b9-9c4d8206e380'	System	19 Mar 2021 16:09:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Mar 2021 16:09:39

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-03-19T11:02:43-05:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dacc0d23-2803-4ca9-b3b9-9c4d8206e380'	System	19 Mar 2021 16:09:39
User entered 'No (N)'	System	19 Mar 2021 16:09:39

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-03-19T11:03:06-05:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dacc0d23-2803-4ca9-b3b9-9c4d8206e380'	System	19 Mar 2021 16:09:39
User entered 'Yes (Y)'	System	19 Mar 2021 16:09:39

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Please 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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-03-19T11:03:14-05:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dacc0d23-2803-4ca9-b3b9-9c4d8206e380'	System	19 Mar 2021 16:09:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Mar 2021 16:09:39

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-03-19T11:03:18-05:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dacc0d23-2803-4ca9-b3b9-9c4d8206e380' User entered '19 Mar 2021 11:03:18'	System	19 Mar 2021 16:09:39
	System	19 Mar 2021 16:09:39

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-04-17T13:40:44-05:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7f794769-4064-4720-81d3-341d02757462'	System	17 Apr 2021 18:40:55
User entered 'No (N)'	System	17 Apr 2021 18:40:55

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-04-17T13:40:48-05:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7f794769-4064-4720-81d3-341d02757462'	System	17 Apr 2021 18:40:55
User entered 'No (N)'	System	17 Apr 2021 18:40:55

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-04-17T13:40:52-05:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7f794769-4064-4720-81d3-341d02757462'	System	17 Apr 2021 18:40:55
User entered '17 Apr 2021 13:40:52'	System	17 Apr 2021 18:40:55

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-04-23T19:42:49-05:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '6b0f5b03-326c-4d3b-a8ff-9465f1c5ba95'	System	24 Apr 2021 00:43:09
User entered 'No (N)'	System	24 Apr 2021 00:43:09

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-04-23T19:42:56-05:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '6b0f5b03-326c-4d3b-a8ff-9465f1c5ba95'	System	24 Apr 2021 00:43:09
User entered 'No (N)'	System	24 Apr 2021 00:43:09

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-04-23T19:43:04-05:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '6b0f5b03-326c-4d3b-a8ff-9465f1c5ba95'	System	24 Apr 2021 00:43:09
User entered '23 Apr 2021 19:43:04'	System	24 Apr 2021 00:43:09

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '09 Nov 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '13 Nov 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '16 Nov 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '20 Nov 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '23 Nov 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '27 Nov 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:14:45

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:31:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-03-08T20:39:21-06:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '2d44a8d5-ec4b-47ce-a8ad-9d647454596f'	System	09 Mar 2021 02:45:07
User entered 'No (N)'	System	09 Mar 2021 02:45:07

US3252516

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:14:45

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:31:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2021-03-08T20:39:27-06:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '2d44a8d5-ec4b-47ce-a8ad-9d647454596f' User entered '08 Mar 2021 20:39:27'	System	09 Mar 2021 02:45:07
	System	09 Mar 2021 02:45:07

US3252516

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:43:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
User entered 'No (N)'	Shannon Moyer (b) (4)	25 Jan 2021 06:26:22
	(b) (4)	

US3252516

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:43:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
User entered empty.	Shannon Moyer (b) (4)	25 Jan 2021 06:26:22
	(b) (4)	

US3252516

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:43:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
User entered empty.	Shannon Moyer (b) (4)	25 Jan 2021 06:26:22
	(b) (4)	

US3252516

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:43:08
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Jan 2021 06:26:22

US3252516

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:43:13
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	25 Jan 2021 06:26:27
	(b) (4)	

US3252516

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:52:05
User entered '1'	System	25 Jan 2021 06:26:27

US3252516

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:01:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:36:15
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	25 Jan 2021 06:26:45

US3252516

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:01:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:36:15
User entered '23 Jan 2021'	Shannon Moyer (b) (4) (b) (4)	25 Jan 2021 06:26:45

US3252516

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:01:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:36:15
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4) (b) (4)	25 Jan 2021 06:26:45

US3252516

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:01:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:36:15
User entered empty.	Shannon Moyer (b) (4) (b) (4)	25 Jan 2021 06:26:45

US3252516

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:01:54
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
User closed query 'Per source, D149 Safety Call was completed 20Feb2021. Please update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 16:29:32
Query 'Per source, D149 Safety Call was completed 20Feb2021. Please update EDC accordingly.' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 09:13:00
User opened query 'Per source, D149 Safety Call was completed 20Feb2021. Please update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 16:37:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:36:22
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	25 Jan 2021 06:26:50

US3252516

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:01:54
User entered '1'	System	25 Jan 2021 06:26:50

US3252516

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:44:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 09:12:33

US3252516

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:44:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
User entered '20 Feb 2021'	(b) (4), (b) (6)	04 Mar 2021 09:12:33

US3252516

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:44:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Mar 2021 09:12:33

US3252516

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:44:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 09:12:33

US3252516

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:44:53
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 09:12:40

US3252516

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:01:54
User entered 'I'	System	04 Mar 2021 09:12:40

US3252516

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:46:04
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 02:27:33

US3252516

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:46:04
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
User entered '19 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 02:27:33

US3252516

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:46:04
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Mar 2021 02:27:33

US3252516

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:46:04
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 02:27:33

US3252516

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:46:10
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 02:27:39

US3252516

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:01:54
User entered 'I'	System	22 Mar 2021 02:27:39

US3252516

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 04:14:02

US3252516

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '17 Apr 2021'	(b) (4), (b) (6)	19 Apr 2021 04:14:02

US3252516

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Apr 2021 04:14:02

US3252516

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	19 Apr 2021 04:14:02

US3252516

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 04:15:10

US3252516

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '17 Apr 2021'	(b) (4), (b) (6)	19 Apr 2021 04:15:10

US3252516

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '11:03'	(b) (4), (b) (6)	19 Apr 2021 04:15:10

US3252516

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '17 Apr 2021 11:03'	System	19 Apr 2021 04:15:10

US3252516

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '98.5' F	(b) (4), (b) (6)	19 Apr 2021 04:15:10

US3252516

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Apr 2021 04:15:10

US3252516

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 04:15:10

US3252516

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '68'	(b) (4), (b) (6)	19 Apr 2021 04:15:10

US3252516

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Apr 2021 04:15:10

US3252516

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '14'	(b) (4), (b) (6)	19 Apr 2021 04:15:10

US3252516

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Apr 2021 04:15:10

US3252516

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '103'	(b) (4), (b) (6)	19 Apr 2021 04:15:10

US3252516

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Apr 2021 04:15:10

US3252516

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '67'	(b) (4), (b) (6)	19 Apr 2021 04:15:10

US3252516

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Apr 2021 04:15:10

US3252516

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 04:15:17

US3252516

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 04:15:17

US3252516

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 04:15:51

US3252516

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 04:15:51

US3252516

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 04:15:51

US3252516

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 04:15:51

US3252516

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 04:15:56

US3252516

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:45

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 04:15:56

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 03:48:31

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '17 Apr 2021'	(b) (4), (b) (6)	19 Apr 2021 03:48:31

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Apr 2021 03:48:31

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:45

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'UNBLND_DECIDE'	System	19 Apr 2021 03:48:31

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:14:45

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '17 Apr 2021'	(b) (4), (b) (6)	19 Apr 2021 03:49:02

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:14:45

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 03:49:02

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:14:45

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 03:49:02

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:14:45

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	19 Apr 2021 03:49:02

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:14:45

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '17 Apr 2021'	(b) (4), (b) (6)	19 Apr 2021 03:49:02

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:14:45

[Participant randomization assignment](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	19 Apr 2021 03:49:02

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:14:45

[Actual Dose 1](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	19 Apr 2021 03:49:02

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:14:45

[Actual Dose 2](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	19 Apr 2021 03:49:02

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:14:45

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 03:49:02

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:14:45

[Placebo Only Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 03:49:02

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:14:45

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 03:49:02

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 03:49:21

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '17 Apr 2021'	(b) (4), (b) (6)	19 Apr 2021 03:49:21

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '11:42'	(b) (4), (b) (6)	19 Apr 2021 03:49:21

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '17 Apr 2021 11:42'	System	19 Apr 2021 03:49:21

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:14:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 03:49:35

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:14:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '17 Apr 2021'	(b) (4), (b) (6)	19 Apr 2021 03:49:35

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:14:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '11:42'	(b) (4), (b) (6)	19 Apr 2021 03:49:35

US3252516

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:14:45

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '17 Apr 2021 11:42'	System	19 Apr 2021 03:49:35

US3252516

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:14:45

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:40:49
User closed query 'Per DM CLR: Per Day 180 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.	(b) (4), (b) (6)	19 Apr 2021 09:10:34
' (Site from DM). Query 'Per DM CLR: Per Day 180 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.	(b) (4), (b) (6)	09 Apr 2021 04:50:49
' answered with 'As per monitors, only COVID-related illness would be added as AEs after D57. If the subject was not having any signs or symptoms of COVID it did not needed to be added as an AE.' (Site from DM). User opened query 'Per DM CLR: Per Day 180 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.	(b) (4), (b) (6)	29 Mar 2021 12:33:38
' (Site from DM). User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:55:35

US3252516

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:14:45

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 19:04:12
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:29:28

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:08:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:29
User entered 'USA-US108-2020-mRNA-1273-P301000004'	System	13 Oct 2020 14:00:26
User entered 'New'	(b) (4), (b) (6)	13 Oct 2020 14:00:26

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:23:14
User coded data point as SOC: Gastrointestinal disorders, HLGIT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis, LLT: Colitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Apr 2021 06:44:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Apr 2021 06:44:55
Data point term sent to Coder	System	27 Apr 2021 06:44:09
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 06:43:13
Coding entries removed.		27 Apr 2021 06:43:13
Signature has been broken.		27 Apr 2021 06:43:13
User entered 'acute COLITIS' reason for change:		27 Apr 2021 06:43:13
Data Entry Error		
User signature succeeded.		05 Apr 2021 20:40:41
DataPoint Verified.		20 Nov 2020 23:47:09
User coded data point as SOC: Gastrointestinal disorders, HLGIT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis, LLT: Colitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 19:10:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 19:10:29
Data point term sent to Coder	System	12 Oct 2020 19:09:21
User entered 'Colitis'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:01:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 14:39:28
	(b) (4), (b) (6)	21 Nov 2020 00:02:07
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'UPDATED' (Site from DM).	Shannon Moyer (b) (4)	18 Nov 2020 09:46:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 09:45:19
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 05:31:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:49:01
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:49:08
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 19:09:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 19:09:14
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 19:09:14
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 19:08:24
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:01:25
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4), (b) (6)	25 Nov 2020 13:54:54
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'This is the time captured in EMR.' (Site from System).	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 21:45:25
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Nov 2020 21:45:10
User entered '00:00' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 21:45:10
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 00:00'	System	24 Nov 2020 21:45:10
User entered empty.	System	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:58:53
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	26 Feb 2021 04:39:42
User entered 'No (N)' reason for change: Data Entry Error	mathew maran (b) (4) (b) (4)	26 Feb 2021 04:39:42
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	26 Feb 2021 04:39:28
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	10 Feb 2021 08:02:35
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	10 Feb 2021 08:01:55
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:20
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'V Query: Please clarify event end dates, as narrative for pneumonia states that subject was discharged from the hospital on 10 Oct 2020 once his symptoms had resolved ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 20:02:27
Query 'V Query: Please clarify event end dates, as narrative for pneumonia states that subject was discharged from the hospital on 10 Oct 2020 once his symptoms had resolved ' answered with 'Per Sub-I, the subject was stable to be discharged from the hospital doesn't mean his illness resolved. He was started on oral antibiotics after he was discharged to continue treatment for his illness. Once the treatment of the PO medications is completed that was the day his illness resolved.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 07:09:05
User opened query 'V Query: Please clarify event end dates, as narrative for pneumonia states that subject was discharged from the hospital on 10 Oct 2020 once his symptoms had resolved ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 21:19:23
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:58:54
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:13:08
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	mathew maran (b) (4) (b) (4)	26 Feb 2021 04:39:49
User entered '20 Oct 2020' reason for change: Data Entry Error	mathew maran (b) (4) (b) (4)	26 Feb 2021 04:39:28
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Feb 2021 08:02:35
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	10 Feb 2021 08:02:35
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 08:02:35

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Feb 2021 08:01:55
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 08:01:55
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 19:50:10
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 18:34:48
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'per source the AE is on going' (Site from Safety).	Shannon Moyer (b) (4) (b) (4)	23 Nov 2020 07:44:44
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 13:18:53
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:56:02
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:25
Query 'PV Query: As the subject was hospitalized, please consider updating severity to grade 4.' canceled (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 13:20:29
User opened query 'PV Query: As the subject was hospitalized, please consider updating severity to grade 4.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 13:20:09
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:44
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:43
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:41
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:03:11
User entered '30 Sep 2020'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:36:37
User closed query 'Per hospital records the discharge date is 10OCT2020 please review. Thank you!' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 18:36:34
Query 'Per hospital records the discharge date is 10OCT2020 please review. Thank you!' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 15:39:00
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 15:38:52
User entered '10 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 15:38:52
User opened query 'Per hospital records the discharge date is 10OCT2020 please review. Thank you!' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 14:11:04
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 14:10:46
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:03:12
User entered '08 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:54
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:55
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:57
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:58
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:51:00
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:03:38
DataPoint Un-verified.		20 Nov 2020 23:52:30
DataPoint Verified.		20 Nov 2020 23:52:29
User entered 'Not Related (NOT RELATED)'		12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:51:07
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:52:40
User entered 'None (NONE)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:52:51
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:52:53
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:52:54
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:59:02
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:13:13
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	mathew maran (b) (4) (b) (4)	26 Feb 2021 04:39:57
DataPoint Un-verified.	mathew maran (b) (4) (b) (4)	26 Feb 2021 04:39:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	mathew maran (b) (4) (b) (4)	26 Feb 2021 04:39:28
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 19:50:19
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 18:34:54
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'per source correct as is' (Site from Safety).	Shannon Moyer (b) (4) (b) (4)	23 Nov 2020 07:45:25
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:53:21
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 13:19:09

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:53:58
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
User closed query 'PV Query: Please provide the clinical course of illness including presenting signs and symptoms. Please leave query open until information is obtained. ' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:13:17
Query 'PV Query: Please provide the clinical course of illness including presenting signs and symptoms. Please leave query open until information is obtained. ' answered with 'Patient was admitted on 30-SEP-2020 and discharged on 08-OCT-2020. Patient reports he was diagnosed with pneumonia while admitted to the hospital as well with colitis. no further information' (Site from Safety).	mathew maran (b) (4)	26 Feb 2021 04:44:02
User opened query 'PV Query: Please provide the clinical course of illness including presenting signs and symptoms. Please leave query open until information is obtained. ' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 12:50:24
User closed query 'PV Query: Please provide the clinical course of illness including (1) signs and symptoms and (2) details of hospitalization. ' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 14:13:27

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the clinical course of illness including (1) signs and symptoms and (2) details of hospitalization. ' answered with 'DURING D22 SAFETY PHONE CALL ON 12-OCT-2020 MR. SUBJECT REPORTED A RECENT HOSPITALIZATION. HE REPORTS BEING DIAGNOSED WITH COLITIS ON 30-SEP-2020 AND WAS HOSPITALIZED FOR A TOTAL OF NINE DAYS. PATIENT WAS REPORTEDLY DISCHARGED FROM VALLEY REGIONAL MEDICAL CENTER ON 08-OCT-2020 AND WAS GIVEN A PRESCRIPTION FOR METRONIDAZOLE 500 MG TID AND LEVOFLOXACIN 500 MG ONCE A DAY. PATIENT STARTED BOTH OF THESE MEDICATIONS YESTERDAY ON 11-OCT-2020. PATIENT WAS SENT A MEDICAL RELEASE FORM VIA EMAIL IN ORDER TO OBTAIN RECORDS FROM HIS HOSPITALIZATION. WILL CONTINUE TO UPDATE INFORMATION AS IT BECOMES AVAILABLE.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 08:05:06
User opened query 'PV Query: Please provide the clinical course of illness including (1) signs and symptoms and (2) details of hospitalization. ' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 21:28:10
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 14:12:30
User closed query 'PV Query: Please provide the clinical course of illness.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 14:12:29
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 14:12:27
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'not done, thanks' (Site from Safety).	Shannon Moyer (b) (4) (b) (4)	04 Feb 2021 08:50:39

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the clinical course of illness.' answered with 'Patient was admitted on 30-SEP-2020 and discharged on 08-OCT-2020' (Site from Safety).	Shannon Moyer (b) (4) (b) (4)	04 Feb 2021 08:47:52
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no data obtainable' (Site from Safety).	Shannon Moyer (b) (4) (b) (4)	04 Feb 2021 08:47:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	21 Nov 2020 00:00:15
User entered 'DURING D22 SAFETY PHONE CALL ON 12-OCT-2020 MR. SUBJECT REPORTED A RECENT HOSPITALIZATION. HE REPORTS BEING DIAGNOSED WITH COLITIS ON 30-SEP-2020 AND WAS HOSPITALIZED FOR A TOTAL OF NINE DAYS. PATIENT WAS REPORTEDLY DISCHARGED FROM VALLEY REGIONAL MEDICAL CENTER ON 08-OCT-2020 AND WAS GIVEN A PRESCRIPTION FOR METRONIDAZOLE 500 MG TID AND LEVOFLOXACIN 500 MG ONCE A DAY. PATIENT STARTED BOTH OF THESE MEDICATIONS YESTERDAY ON 11-OCT-2020. PATIENT WAS SENT A MEDICAL RELEASE FORM VIA EMAIL IN ORDER TO OBTAIN RECORDS FROM HIS HOSPITALIZATION. WILL CONTINUE TO UPDATE INFORMATION AS IT BECOMES AVAILABLE.' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 20:33:56
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	21 Oct 2020 13:19:54
User opened query 'PV Query: Please provide the clinical course of illness.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	21 Oct 2020 13:19:46
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	21 Oct 2020 13:19:28

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Narrative](#)

Audit	User	Time (GMT)
User entered 'During D22 Safety Phone Call on 12-OCT-2020 Mr. (b) (6) reported a recent hospitalization. He reports being diagnosed with Colitis on 30-SEP-2020 and was hospitalized for a total of nine days. Patient was reportedly discharged from Valley Regional Medical Center on 08-OCT-2020 and was given a prescription for Metronidazole 500 mg TID and Levofloxacin 500 mg once a day. Patient started both of these medications yesterday on 11-OCT-2020. Patient was sent a medical release form via email in order to obtain records from his hospitalization. Will continue to update information as it becomes available.'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:45

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:01:25
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:30:02
User entered 'USA-US108-2020-mRNA-1273-P301000004'	(b) (4), (b) (6)	21 Oct 2020 20:29:58

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:05:45
User coded data point as SOC: Infections and infestations, HLGT: Mycoplasmal infectious disorders, HLT: Mycoplasma infections, PT: Pneumonia mycoplasmal, LLT: Pneumonia due to mycoplasma pneumoniae - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 14:30:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 14:30:17
Data point term sent to Coder	System	23 Apr 2021 05:16:02
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 05:15:30
Coding entries removed.		23 Apr 2021 05:15:30
Signature has been broken.		23 Apr 2021 05:15:30
User entered 'Bilateral multifocal pneumonia right greater than left due to mycoplasma pneumonia' reason for change: Data Entry Error		23 Apr 2021 05:15:30
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:01:26
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 22:22:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 22:22:32
Data point term sent to Coder	System	20 Oct 2020 22:21:22
User entered 'Pneumonia'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:03:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
User closed query 'Per CDM: Was this a Solicited Adverse Reaction? = Yes. However, "PNEUMONIA" is not a solicited event for this study. Please review and update accordingly. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:39:56
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:04:04
Query 'Per CDM: Was this a Solicited Adverse Reaction? = Yes. However, "PNEUMONIA" is not a solicited event for this study. Please review and update accordingly. Otherwise, clarify' answered with 'UPDATED' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:53:05
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:52:47
User opened query 'Per CDM: Was this a Solicited Adverse Reaction? = Yes. However, "PNEUMONIA" is not a solicited event for this study. Please review and update accordingly. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 09:56:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:09:10
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:09:13
User entered '30 Sep 2020'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:56:05
User closed query 'Per eCRF completion guidelines, time should only be entered for adverse events within 24 hours after dosing. Please review and enter data conformant with CCGs.' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 20:56:04
Query 'Per eCRF completion guidelines, time should only be entered for adverse events within 24 hours after dosing. Please review and enter data conformant with CCGs.' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 07:54:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 07:54:24
User opened query 'Per eCRF completion guidelines, time should only be entered for adverse events within 24 hours after dosing. Please review and enter data conformant with CCGs.' (Site from CRA).	(b) (4), (b) (6)	08 Jan 2021 05:00:39
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 04:59:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:08:52
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4), (b) (6)	25 Nov 2020 13:55:20
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'this is the time in our emr.' (Site from System).	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 21:56:58
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Nov 2020 21:55:58
User entered '00:00' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 21:55:58
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Feb 2021 07:54:24
User entered '30 Sep 2020 00:00'	System	24 Nov 2020 21:55:58
User entered empty.	System	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:56:07
User entered 'No (N)' reason for change: Data Entry Error	mathew maran (b) (4)	26 Feb 2021 04:44:49
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 19:08:57
DataPoint Verified.		03 Dec 2020 19:08:53
User entered 'Yes (Y)'		20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify event end dates, as narrative for pneumonia states that subject was discharged from the hospital on 10 Oct 2020 once his symptoms had resolved ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 19:55:34
Query 'PV Query: Please clarify event end dates, as narrative for pneumonia states that subject was discharged from the hospital on 10 Oct 2020 once his symptoms had resolved ' answered with 'Per Sub-I, the subject was stable to be discharged from the hospital doesn't mean his illness resolved. He was started on oral antibiotics after he was discharged to continue treatment for his illness. Once the treatment of the PO medications is completed that was the day his illness resolved.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 07:09:16
User opened query 'PV Query: Please clarify event end dates, as narrative for pneumonia states that subject was discharged from the hospital on 10 Oct 2020 once his symptoms had resolved ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 21:18:53
User signature succeeded. DataPoint Verified.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
	(b) (4), (b) (6)	26 Feb 2021 20:56:09
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:13:44
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	mathew maran (b) (4)	26 Feb 2021 04:44:59
	(b) (4)	
User entered '20 Oct 2020' reason for change: Data Entry Error	mathew maran (b) (4)	26 Feb 2021 04:44:49
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:52:21
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:56:21
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:10:37
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:10:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:10:49
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:10:51
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:10:52
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	20 Oct 2020 22:21:59
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	20 Oct 2020 22:21:59
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	20 Oct 2020 22:20:27
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:10:54
User entered '30 Sep 2020'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 12:56:32
User closed query 'Per med records (page 2) the discharge date is 10OCT2020. Please review. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 12:56:30
Query 'Per med records (page 2) the discharge date is 10OCT2020. Please review. ' answered with 'updated as per query' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 03:08:20
User entered '10 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 03:07:55
User opened query 'Per med records (page 2) the discharge date is 10OCT2020. Please review. ' (Site from CRA).	(b) (4), (b) (6)	25 Apr 2021 21:30:22
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:18:20
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 07:18:20
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 07:18:20
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:10:55
User entered '8 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:10:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 22:21:59
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:10:59
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:11:01
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:11:02
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:11:03
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:09:02
DataPoint Un-verified.		21 Nov 2020 00:15:38
DataPoint Verified.		21 Nov 2020 00:11:05
User entered 'Not Related (NOT RELATED)'		20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:11:07
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:11:08
User entered 'None (NONE)'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:49:21
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 02:22:35
User entered '0' reason for change: New Information	(b) (4), (b) (6)	19 Apr 2021 02:22:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	08 Mar 2021 02:53:52
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	08 Mar 2021 02:49:42
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 07:54:24
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 07:54:24
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:11:41
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 22:24:33
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:49:22
User closed query '-Action Taken with IP is None: This is correct. -Other Action Taken: Should be checked in box for Concomitant Medication as Levofloxacin was administered for Pneumonia. Please update the CRF accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 13:49:15
Query '-Action Taken with IP is None: This is correct. -Other Action Taken: Should be checked in box for Concomitant Medication as Levofloxacin was administered for Pneumonia. Please update the CRF accordingly.' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 02:22:57
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 02:22:35
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 02:22:35
User entered '1' reason for change: New Information	(b) (4), (b) (6)	19 Apr 2021 02:22:35
User opened query '-Action Taken with IP is None: This is correct. -Other Action Taken: Should be checked in box for Concomitant Medication as Levofloxacin was administered for Pneumonia. Please update the CRF accordingly.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 16:29:29
User closed query 'Per source, it is recorded that "Other action taken" is "Concomitant Medication". Please review source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:24:20
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:24:18
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
User entered '0' reason for change: Data Entry Error	mathew maran (b) (4)	08 Mar 2021 02:53:52
User entered '1' reason for change: Data Entry Error	mathew maran (b) (4)	08 Mar 2021 02:49:42
Query 'Per source, it is recorded that "Other action taken" is "Concomitant Medication". Please review source and update EDC accordingly.' answered with 'Per source, it is recorded that "Other action taken" is "NONE for pneumonia , thanks' (Site from CRA).	mathew maran (b) (4)	08 Mar 2021 02:47:49

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per source, it is recorded that "Other action taken" is "Concomitant Medication". Please review source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 20:57:25
User closed query 'Per records, patient received Metronidazole 500 mg and Levofloxacin 500mg for both Colitis and Pneumonia. Please review Conmed log and update conmed log as appropriate.' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 20:57:25
User closed query 'Per DM CLR-RQ: Response noted. However, please include "PNEUMONIA" as indication for both Metronidazole and Levofloxacin. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 13:14:14
User closed query 'Per CDM: Concomitant medication "checked" however concomitant medication record for Adverse Event 'PNEUMONIA' is missing from the Concomitant Medication form. Please review/provide or clarify otherwise. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 12:32:29
Query 'Per records, patient received Metronidazole 500 mg and Levofloxacin 500mg for both Colitis and Pneumonia. Please review Conmed log and update conmed log as appropriate.' answered with 'Action Taken with Study Medication is NONE as per the source' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 07:56:00
Query 'Per DM CLR-RQ: Response noted. However, please include "PNEUMONIA" as indication for both Metronidazole and Levofloxacin. Update as appropriate.' answered with 'Action Taken with Study Medication is NONE as per the source' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 07:55:55
Query 'Per CDM: Concomitant medication "checked" however concomitant medication record for Adverse Event 'PNEUMONIA' is missing from the Concomitant Medication form. Please review/provide or clarify otherwise. ' answered with 'Action Taken with Study Medication is NONE as per the source' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 07:55:37
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 07:54:24
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 07:54:24

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR-RQ: Response noted. However, please include "PNEUMONIA" as indication for both Metronidazole and Levofloxacin. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 18:19:59
User opened query 'Per records, patient received Metronidazole 500 mg and Levofloxacin 500mg for both Colitis and Pneumonia. Please review Conmed log and update conmed log as appropriate.' (Site from CRA).	(b) (4), (b) (6)	08 Jan 2021 05:02:03
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 05:00:47
DataPoint Un-verified.		03 Dec 2020 19:09:28
User opened query 'Per CDM: Concomitant medication "checked" however concomitant medication record for Adverse Event 'PNEUMONIA' is missing from the Concomitant Medication form. Please review/provide or clarify otherwise. ' (Site from DM).		30 Nov 2020 04:36:20
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:11:42
User entered '1' reason for change: Data Entry Error		20 Oct 2020 22:24:33
User entered '0'		20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide name and results of procedure performed on 30 Sep 2020. If not available, please state so.' answered with 'the medical records are not available. con procedures are updated' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 06:15:24
User opened query 'PV Query: Please provide name and results of procedure performed on 30 Sep 2020. If not available, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:24:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 19:09:33
DataPoint Verified.		21 Nov 2020 00:11:44
User entered '0'		20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:57:30
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:13:48
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	mathew maran (b) (4) (b) (4)	26 Feb 2021 04:45:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	mathew maran (b) (4) (b) (4)	26 Feb 2021 04:44:49
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:52:42
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 22:21:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 22:21:59
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 22:21:59
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 22:20:27
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:13:18
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:06:26
User closed query 'PV Query: Please review if hypoxemia should be reported as an SAE ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 19:30:37
Query 'PV Query: Please review if hypoxemia should be reported as an SAE ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 05:18:08
User closed query 'PV Query: Please clarify date of hospital discharge, narrative for pneumonia states that he was discharged on 10 Oct 2020, but narrative for colitis and other information indicates he was discharged on 08 Oct 2020. ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 19:57:05
Query 'PV Query: Please clarify date of hospital discharge, narrative for pneumonia states that he was discharged on 10 Oct 2020, but narrative for colitis and other information indicates he was discharged on 08 Oct 2020. ' answered with 'It has been corrected.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 07:27:36
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:26:44
User entered 'DURING D22 SAFETY CALL ON THE 12TH OF OCT 2020 SUBJECT REPORTED HE WAS RECENTLY HOSPITALIZED ON THE 30TH OF SEP 2020 AND DISCHARGE ON THE 8TH OF OCT 2020. SUBJECT PRESENTED TO HIS LOCAL EMERGENCY DEPARTMENT DUE TO A THREE-DAY HISTORY OF WATER STOOL, COUGH, AND SHORTNESS OF BREATH ON THE 30TH OF SEP 2020. SUBJECT WAS DIAGNOSES WITH PNEUMONIA, HYPOXEMIA AND COLITIS. SUBJECT WAS ADMITTED TO THE HOSPITAL FOR TREATMENT AND DISCHARGE ON OCT 8TH 2020 ONCE HIS SYMPTOMS RESOLVED. SUBJECT WAS STARTED ON LEVOFLOXACIN 500MG ONCE DAILY AND METRONIDAZOLE 500 MG THREE TIMES DAILY FOR THE NEXT FIVE DAYS. SUBJECT REPORTS HE STARTED THE MEDICATIONS ON THE 11TH OF OCT 2020.' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 07:26:44

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please review if hypoxemia should be reported as an SAE ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 21:19:02
User opened query 'PV Query: Please clarify date of hospital discharge, narrative for pneumonia states that he was discharged on 10 Oct 2020, but narrative for colitis and other information indicates he was discharged on 08 Oct 2020. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:18:39
User closed query 'Narrative is in EDC but is not located in source. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 16:23:28
Query 'Narrative is in EDC but is not located in source. Please review and reconcile. ' answered with 'source is updated ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 16:23:26
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 19:48:22
User entered 'During D22 Safety call on the 12th of OCT 2020 Subject reported he was recently hospitalized on the 30th of SEP 2020 and discharge on the 10th of OCT 2020. Subject presented to his local emergency department due to a three-day history of water stool, cough, and shortness of breath on the 30th of SEP 2020. Subject was diagnoses with pneumonia, hypoxemia and colitis. Subject was admitted to the hospital for treatment and discharge on OCT 10th 2020 once his symptoms resolved. Subject was started on Levofloxacin 500mg once daily and Metronidazole 500 mg three times daily for the next five days. Subject reports he started the medications on the 11th of OCT 2020.' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 19:48:09
User opened query 'Narrative is in EDC but is not located in source. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:25:33
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 15:25:15
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Narrative](#)

Audit	User	Time (GMT)
User closed query ' PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 16:10:36
Query ' PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no documents available' (Site from Safety).	mathew maran (b) (4)	24 Mar 2021 07:58:56
User closed query ' PV Query: Please provide the clinical course of illness.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:13:51
Query ' PV Query: Please provide the clinical course of illness.' answered with 'Patient was placed on Metronidazole 500mg TID and Levofloxacin 500 mg once a day. Patient was admitted on 30-SEP-2020 and discharged on 08-OCT-2020. AE started on 30 sep 2020 and ended on 20 oct 2020' (Site from Safety).	mathew maran (b) (4)	26 Feb 2021 04:47:04
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:09:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Nov 2020 00:13:07
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:13:03
User opened query ' PV Query: Please provide the clinical course of illness.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:53:24
User opened query ' PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:53:06
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Oct 2020 22:24:33
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	20 Oct 2020 22:24:33
User entered 'During D29 visit, patient reported he was diagnosed with pneumonia along with colitis and was admitted to the hospital. Colitis was already recorded on safety call however he did not report the pneumonia. Medical release record has been signed and updates will be provided once more information is available.' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 22:24:33

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Oct 2020 22:20:27
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:45

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Oct 2020 22:21:59

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[AEID](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 17:20:22
DataPoint Verified.		30 Apr 2021 17:20:20
Reviewed for Safety.		19 Apr 2021 14:06:02
User entered 'USA-US108-2021-mRNA-1273-P301000020'	System	19 Apr 2021 14:05:57
User entered 'New'	(b) (4), (b) (6)	19 Apr 2021 14:05:57

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Adverse event](#)

Audit	User	Time (GMT)
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'the medical records are still pending' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 05:54:03
Query 'PV Query: Please confirm if SAE #3 and 4 are two separate events or if they are the same event. If it is just one event, please reconcile accordingly.' answered with 'according to the sub PI, both are different events' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 05:51:50
User opened query 'PV Query: Please confirm if SAE #3 and 4 are two separate events or if they are the same event. If it is just one event, please reconcile accordingly.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:31:30
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:26:18
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Heart rate and pulse investigations, PT: Heart rate irregular, LLT: Heartbeats irregular - version MedDRA\23.0.	Coder Import (b) (4)	16 Apr 2021 21:39:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Apr 2021 21:39:55
Data point term sent to Coder	System	16 Apr 2021 21:39:20
User entered 'irregular heart beat'	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 02:25:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 02:25:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 02:25:17
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:39:19
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 02:25:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 02:25:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 02:25:17
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:39:19
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 02:25:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 02:25:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 02:25:17
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:39:19
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please specify event onset date. If unknown, please indicate so. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 18:34:40
Query 'PV Query: Please specify event onset date. If unknown, please indicate so. ' answered with 'date is unknown' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 06:47:36
User opened query 'PV Query: Please specify event onset date. If unknown, please indicate so. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:26:07
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	KC Joubran (b) (4) (b) (4)	23 Apr 2021 13:28:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Apr 2021 05:21:07
User entered 'UN Apr 2021' (non-conformant).	(b) (4), (b) (6)	23 Apr 2021 05:21:07
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Apr 2021 05:19:18
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 05:19:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Apr 2021 21:39:19
User entered 'UN Apr 2021' (non-conformant).	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	23 Apr 2021 05:19:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 05:19:39
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	23 Apr 2021 05:19:18
User entered '00:00'	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 05:19:39
User entered '30 Sep 2020 00:00'	System	23 Apr 2021 05:19:18
User entered 'UN Apr 2021 00:00' (non-conformant).	System	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please specify event end date. If unknown, please indicate so. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 18:34:44
Query 'PV Query: Please specify event end date. If unknown, please indicate so. ' answered with 'date is unknown' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 06:47:46
User opened query 'PV Query: Please specify event end date. If unknown, please indicate so. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:25:52
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	KC Joubran (b) (4) (b) (4)	23 Apr 2021 13:28:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Apr 2021 05:21:07
User entered 'UN Apr 2021' (non-conformant).	(b) (4), (b) (6)	23 Apr 2021 05:21:07
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Apr 2021 05:19:18
User entered '20 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 05:19:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Apr 2021 21:39:19
User entered 'UN Apr 2021' (non-conformant).	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	23 Apr 2021 05:19:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 05:19:52
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	23 Apr 2021 05:19:18
User entered '00:00'	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 05:19:52
User entered '20 Oct 2020 00:00'	System	23 Apr 2021 05:19:18
User entered 'UN Apr 2021 00:00' (non-conformant).	System	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Severity](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 02:25:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 02:25:17
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 02:25:17
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:39:19
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

Death

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 09:53:51
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	22 Apr 2021 07:14:18
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	16 Apr 2021 21:39:19
User entered '1'	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '05 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	22 Apr 2021 07:14:01
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	22 Apr 2021 07:14:01
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 02:25:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 02:25:17
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 02:25:17
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:39:19
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 02:25:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 02:25:17
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 02:25:17
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:39:19
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: As the last dose of study drug was given on 20 Oct 2020, please update the action taken with study drug from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 18:34:57
Query 'PV Query: As the last dose of study drug was given on 20 Oct 2020, please update the action taken with study drug from none to not applicable. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 06:48:38
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Apr 2021 06:48:29
User opened query 'PV Query: As the last dose of study drug was given on 20 Oct 2020, please update the action taken with study drug from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:15:29
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 02:25:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 02:25:17
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 02:25:17
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:39:19
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Apr 2021 02:25:17
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 02:25:17
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Apr 2021 21:39:19
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:23:07
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 02:25:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 02:25:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 02:25:17
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:39:19
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:22:57
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:22:44
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 21:39:19

US3252516

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:45

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 02:25:17

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:06:36
User entered 'USA-US108-2021-mRNA-1273-P301000020'	(b) (4), (b) (6)	19 Apr 2021 14:06:31

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Adverse event](#)

Audit	User	Time (GMT)
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'the medical records are not available for now' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 06:16:36
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:27:56
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Heart rate and pulse investigations, PT: Heart rate irregular, LLT: Heartbeats irregular - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 21:43:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 21:43:05
Data point term sent to Coder	System	16 Apr 2021 21:41:33
User entered 'irregular heart beat'	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 02:29:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 02:29:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 02:29:04
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:41:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 02:29:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 02:29:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 02:29:04
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:41:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 02:29:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 02:29:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 02:29:04
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:41:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please specify event onset date. If unknown, please indicate so.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 18:35:20
Query 'PV Query: Please specify event onset date. If unknown, please indicate so.' answered with 'date is unknown' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 06:48:53
User opened query 'PV Query: Please specify event onset date. If unknown, please indicate so.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:28:10
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	KC Joubran (b) (4) (b) (4)	23 Apr 2021 13:29:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Apr 2021 02:29:04
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Apr 2021 02:29:04
User entered 'un Apr 2021' (non-conformant).	(b) (4), (b) (6)	19 Apr 2021 02:29:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Apr 2021 21:41:00
User entered ' Apr 2021' (non-conformant).	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered '00:00'	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered 'UN Apr 2021 00:00' (non-conformant).	System	19 Apr 2021 02:29:04
User entered ' Apr 2021 00:00' (non-conformant).	System	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please specify event end date. If unknown, please indicate so. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 18:35:24
Query 'PV Query: Please specify event end date. If unknown, please indicate so. ' answered with 'date is unknown' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 06:48:56
User opened query 'PV Query: Please specify event end date. If unknown, please indicate so. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:28:30
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	KC Joubran (b) (4)	23 Apr 2021 13:29:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	19 Apr 2021 02:29:04
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Apr 2021 02:29:04
User entered 'un Apr 2021' (non-conformant).	(b) (4), (b) (6)	19 Apr 2021 02:29:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Apr 2021 21:41:00
User entered ' Apr 2021' (non-conformant).	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Severity](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 02:29:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 02:29:04
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 02:29:04
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:41:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 09:56:28
User opened query 'Per CDM: Please update the Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? as soon as they are available.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 09:56:19
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'awaiting medical records to finalize dates' (Site from System).	(b) (4), (b) (6)	23 Apr 2021 21:39:56
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	16 Apr 2021 21:41:00
User entered '1'	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the hospital admission date. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:28:46
Query 'Please provide the hospital admission date. ' canceled (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:16:26
User opened query 'Please provide the hospital admission date. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:16:25
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:28:54
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 02:29:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 02:29:04
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 02:29:04
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:41:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 02:29:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 02:29:04
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 02:29:04
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:41:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: As the last dose of study drug was given on 20 Oct 2020, please update the action taken with study drug from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 18:35:32
Query 'PV Query: As the last dose of study drug was given on 20 Oct 2020, please update the action taken with study drug from none to not applicable. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 06:49:36
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Apr 2021 06:49:26
User opened query 'PV Query: As the last dose of study drug was given on 20 Oct 2020, please update the action taken with study drug from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:15:51
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 02:29:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 02:29:04
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 02:29:04
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:41:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Apr 2021 02:29:04
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 02:29:04
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Apr 2021 21:41:00
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:29:36
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 02:29:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 02:29:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 02:29:04
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:41:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:29:51
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' canceled (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:29:28
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:29:21
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:29:08
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 21:41:00

US3252516

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:14:45

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 02:29:04

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:32:10
Reviewed for Safety.		23 Apr 2021 19:11:56
User entered 'USA-US108-2020-mRNA-1273-P301000004'		23 Apr 2021 19:11:23

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:07:58
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Hypoxic respiratory failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 12:16:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 12:16:11
Data point term sent to Coder	System	23 Apr 2021 05:24:07
User entered 'Hypoxemia respiratory failure on admission, resolved'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:10:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:31:09
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:31:10
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:31:12
User entered '30 Sep 2020'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:31:14
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	23 Apr 2021 05:23:46
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 05:23:46
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	23 Apr 2021 05:23:27
User entered '21:03'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 05:23:46
User entered '30 Sep 2020 21:03'	System	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:31:16
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:10:38
User entered '10 Oct 2020'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:32:07
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:32:06
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:31:37
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	23 Apr 2021 05:24:31
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	23 Apr 2021 05:23:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:11:41
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:11:40
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 09:56:42
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'dates have been changed' (Site from System).	(b) (4), (b) (6)	23 Apr 2021 21:39:21
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	23 Apr 2021 05:24:31
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 05:24:31
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:11:34
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 21:39:06
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 12:57:18
User closed query 'per page 2 of medical records, the discharge date was 10OCT2020. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 12:57:15
Query 'per page 2 of medical records, the discharge date was 10OCT2020. Please review and reconcile. ' answered with 'updated as per query' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 03:09:29
User entered '10 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 03:09:13
User opened query 'per page 2 of medical records, the discharge date was 10OCT2020. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	25 Apr 2021 21:12:29
Query 'per page 2 of medical records, the discharge date was 10OCT2020. Please review and reconcile. ' canceled (Site from CRA).	(b) (4), (b) (6)	25 Apr 2021 21:12:02
User opened query 'per page 2 of medical records, the discharge date was 10OCT2020. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	25 Apr 2021 21:11:20
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 21:39:06
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:11:44
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:11:45
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:11:58
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:11:56
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:11:55
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:11:50
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:11:51
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:11:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:31:23
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:31:25
User entered '1'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:31:27
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:31:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:31:32
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:31:33
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:14:45

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 05:23:27

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:20:43
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 14:04:12

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:24:27
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Bilateral pleural effusion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Apr 2021 08:10:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Apr 2021 08:10:06
Data point term sent to Coder	System	27 Apr 2021 06:45:10
User entered 'small bilateral pleural effusions'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:24:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:24:32
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:24:34
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query - source indicates a three day history of symptoms before subject reported to the ER on 30 Sep 2020. Consider revising start date for events.' answered with 'as per the source "initial emergency room note states patient had a 3 day history of "watery diarrhea, anxiety, palpitations, and a feeling of "shaky". The adverse events reported on source were diagnosed the day of admission or several days later.'" (Site from Safety).	(b) (4), (b) (6)	04 May 2021 03:00:26
User opened query 'PV Query - source indicates a three day history of symptoms before subject reported to the ER on 30 Sep 2020. Consider revising start date for events.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 14:03:49
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:24:52
User entered '30 Sep 2020'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:24:53
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:24:55
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:24:57
User entered '10 Oct 2020'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:24:58
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:25:00
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:25:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:25:03
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:25:06
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:25:08
User entered '1'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:25:09
User entered '30 Sep 2020'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:25:10
User entered '10 Oct 2020'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:25:12
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:25:13
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:25:19
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:25:18
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:25:27
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:25:29
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:25:32
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

Action taken with investigational product

Audit	User	Time (GMT)
Query 'PV Query: For the event small bilateral pleural effusions, please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 21 Sep 2020, then event occurred).' answered with 'updated' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	04 May 2021 03:09:04
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 May 2021 03:08:59
User opened query 'PV Query: For the event small bilateral pleural effusions, please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 21 Sep 2020, then event occurred).' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 14:03:16
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	29 Apr 2021 18:25:34
		27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:25:41
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:26:54
User entered '1'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:25:51
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:26:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:26:50
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:26:52
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 06:45:06

US3252516

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:14:45

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Apr 2021 06:45:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:14:45

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:40:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:56:44
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:25:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:59:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, NON-SELECTIVE, PRODUCT: PROPRANOLOL, PRODUCTSYNONYM: PROPANOLOL [PROPRANOLOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:27:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:27:56
Data point term sent to Coder	System	22 Sep 2020 05:26:30
User entered 'Propranolol'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:59:44
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:59:45
User entered 'Hypertension'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:59:47
User entered '10'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:59:49
User entered 'mg (mg)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:59:52
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:59:57
User entered 'once daily (QD)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:00:15
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:00:17
User entered 'Oral (ORAL)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:00:31
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:00:34
User entered 'UN UNK 2010'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:45

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:00:36
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:00:40
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:00:42
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:00:46
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 05:26:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 05:26:31
User entered 'No (N)' reason for change: Data Entry Error	Nancy Torrence (b) (4)	22 Sep 2020 05:26:31
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 05:26:01
User entered empty.	Nancy Torrence (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:01:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: SITAGLIPTIN, PRODUCTSYNONYM: JANUVIA [SITAGLIPTIN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:29:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:29:48
Data point term sent to Coder	System	22 Sep 2020 05:29:31
User entered 'Januvia'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:01:19
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:01:20
User entered 'Type II Diabetes Mellitus'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:01:22
User entered '50'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:01:23
User entered 'mg (mg)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:01:25
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:01:26
User entered 'once daily (QD)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:01:28
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:01:30
User entered 'Oral (ORAL)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:03:14
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:03:15
User entered 'UN UNK 2010'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:03:17
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:03:19
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:03:21
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 21:03:22
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:04:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 05:41:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 05:41:25
Data point term sent to Coder	System	13 Oct 2020 03:05:00
Data point term sent to Coder	System	13 Oct 2020 03:04:00
User entered 'Metronidazole'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:04:27
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:45

Indication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:04:25
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 03:04:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 03:04:11
User entered 'Colitis' reason for change: Data Entry Error	Nancy Torrence (b) (4)	13 Oct 2020 03:04:11
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 03:03:47
User entered empty.	Nancy Torrence (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:04:31
User entered '500'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:04:35
User entered 'mg (mg)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:04:37
User entered empty.	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:04:39
User entered 'three times daily (TID)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:04:43
User entered empty.	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:04:42
User entered 'Oral (ORAL)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:04:44
User entered empty.	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:04:46
User entered '11 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:04:47
User entered '0'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:33:45
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 07:18:47
DataPoint Un-verified.		20 Apr 2021 07:16:31
Signature has been broken.		20 Apr 2021 07:16:31
User entered 'Yes (Y)' reason for change: Data Entry Error		20 Apr 2021 07:16:31
DataPoint Verified.		15 Apr 2021 16:19:53
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 10:43:32
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 09:14:48
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 09:14:40
Signature has been broken.		11 Mar 2021 09:14:40
User entered 'No (N)' reason for change: Data Entry Error		11 Mar 2021 09:14:40
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:01:26
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:04:49
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:33:47
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '20 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 07:18:47
DataPoint Un-verified.		20 Apr 2021 07:16:31
Signature has been broken.		20 Apr 2021 07:16:31
User entered empty; reason for change Data Entry Error		20 Apr 2021 07:16:31
DataPoint Verified.		15 Apr 2021 16:19:55
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 09:14:40
Signature has been broken.		11 Mar 2021 09:14:40
User entered '20 Oct 2020' reason for change: Data Entry Error		11 Mar 2021 09:14:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:04:50
User entered empty.	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:04:52
User closed query 'Per CDM: "Was this medication taken for solicited event?" Is recorded as "YES" however Indication (COLITIS) is not listed in the solicited events as per protocol. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 09:03:57
User entered 'No (N)' reason for change: Data Entry Error	Nancy Torrence (b) (4)	05 Nov 2020 03:57:29
Query 'Per CDM: "Was this medication taken for solicited event?" Is recorded as "YES" however Indication (COLITIS) is not listed in the solicited events as per protocol. Please review and update accordingly' answered with 'Solicited event indication updated.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 21:55:43
User opened query 'Per CDM: "Was this medication taken for solicited event?" Is recorded as "YES" however Indication (COLITIS) is not listed in the solicited events as per protocol. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 13:29:16
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:45

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:09:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:09:52
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	20 Apr 2021 07:15:19 20 Apr 2021 07:14:50
User signature succeeded. DataPoint Verified.	Joel Solis (b) (4) (b) (4), (b) (6)	05 Mar 2021 22:09:26 03 Dec 2020 19:05:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 05:39:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 05:39:25
Data point term sent to Coder User entered 'Levofloxacin'	System Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:06:01 13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:05:01
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:11:14
User closed query 'Per source the indication for this ConMed was Pneumonia. Please reconcile and update the CRF accordingly. ' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 21:11:13
Query 'Per source the indication for this ConMed was Pneumonia. Please reconcile and update the CRF accordingly. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 07:18:09
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 07:14:50
User entered 'COLITIS,pneumonia' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 07:14:50
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 16:32:41
User opened query 'Per source the indication for this ConMed was Pneumonia. Please reconcile and update the CRF accordingly. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 16:32:38
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:05:03
User entered 'Colitis'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:05:05
User entered '500'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:05:07
User entered 'mg (mg)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:05:09
User entered empty.	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:05:11
User entered 'once daily (QD)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:05:12
User entered empty.	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:05:14
User entered 'Oral (ORAL)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:05:16
User entered empty.	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:05:18
User entered '11 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:05:20
User entered '0'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:34:11
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 10:43:38
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 09:15:51
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 09:15:45
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 09:15:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 09:15:45
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:01:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:05:22
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:34:12
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 09:15:45
Signature has been broken.		11 Mar 2021 09:15:45
User entered '20 Oct 2020' reason for change: Data Entry Error		11 Mar 2021 09:15:45
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:05:23
User entered empty.	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:05:25
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:45

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:57:06
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Apr 2021 06:21:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Apr 2021 06:21:02
Data point term sent to Coder	System	27 Apr 2021 06:19:48
User entered 'trazadone'	(b) (4), (b) (6)	27 Apr 2021 06:19:37

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:57:08
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Apr 2021 06:19:37

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:57:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'insomnia'	(b) (4), (b) (6)	27 Apr 2021 06:19:37

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:57:11
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '200'	(b) (4), (b) (6)	27 Apr 2021 06:19:37

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:57:13
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Apr 2021 06:19:37

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:57:14
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:19:37

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:57:16
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Apr 2021 06:19:37

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:57:18
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:19:37

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:57:21
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Apr 2021 06:19:37

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:57:31
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:19:37

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:57:30
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'un Apr 2010'	(b) (4), (b) (6)	27 Apr 2021 06:19:37

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:45

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:57:28
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:19:37

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User closed query 'Trazadone 100mg is reported as starting in April 2020, please confirm if 200mg dosage has a discontinuation date. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:21:31
Query 'Trazadone 100mg is reported as starting in April 2020, please confirm if 200mg dosage has a discontinuation date. ' answered with 'updated' (Site from CRA). Signature has been broken.	(b) (4), (b) (6)	30 Apr 2021 17:21:28
	(b) (4), (b) (6)	30 Apr 2021 15:31:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 15:30:50
User opened query 'Trazadone 100mg is reported as starting in April 2020, please confirm if 200mg dosage has a discontinuation date. ' (Site from CRA). Query 'Trazadone 100mg is reported as starting in April 2021, please confirm if 200mg dosage has a discontinuation date. ' canceled (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 15:30:50
User opened query 'Trazadone 100mg is reported as starting in April 2021, please confirm if 200mg dosage has a discontinuation date. ' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 18:06:52
	(b) (4), (b) (6)	29 Apr 2021 18:06:40
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:03:52
	(b) (4), (b) (6)	29 Apr 2021 18:03:14
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Apr 2021 06:19:37

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:21:26
DataPoint Un-verified.		30 Apr 2021 15:30:50
Signature has been broken.		30 Apr 2021 15:30:50
User entered '10 Oct 2020' reason for change: Data Entry Error		30 Apr 2021 15:30:50
DataPoint Verified.		29 Apr 2021 17:57:25
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:19:37

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:57:24
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:19:37

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 06:19:37

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 06:19:37

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Apr 2021 06:19:37

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:45

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:59:02
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: LEVETIRACETAM, PRODUCTSYNONYM: KEPPRA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Apr 2021 06:22:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Apr 2021 06:22:05
Data point term sent to Coder	System	27 Apr 2021 06:20:51
User entered 'keppra'	(b) (4), (b) (6)	27 Apr 2021 06:20:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:59:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:20:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'seizures'	(b) (4), (b) (6)	27 Apr 2021 06:20:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:59:07
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '500'	(b) (4), (b) (6)	27 Apr 2021 06:20:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:59:09
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Apr 2021 06:20:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:59:10
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:20:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:59:12
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'twice daily (BID)'	(b) (4), (b) (6)	27 Apr 2021 06:20:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:59:13
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:20:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:59:15
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Apr 2021 06:20:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:20:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:59:18
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '30 Sep 2014'	(b) (4), (b) (6)	27 Apr 2021 06:20:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:45

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:59:19
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:20:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:21:47
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 07:01:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 07:01:39
User entered 'Yes (Y)' reason for change: New Information	mathew maran (b) (4) (b) (4)	30 Apr 2021 07:01:39
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 07:00:11
Signature has been broken.	mathew maran (b) (4) (b) (4)	30 Apr 2021 07:00:11
User entered empty; reason for change Data Entry Error	mathew maran (b) (4) (b) (4)	30 Apr 2021 07:00:11
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 17:59:22
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:58:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:20:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:21:50
User closed query 'Per source, ongoing. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 17:21:48
Query 'Per source, ongoing. Please review and reconcile. ' answered with 'updated per source, thanks' (Site from CRA).	mathew maran (b) (4)	30 Apr 2021 07:01:50
Signature has been broken.	mathew maran (b) (4)	30 Apr 2021 07:00:11
User entered empty; reason for change Data Entry Error	mathew maran (b) (4)	30 Apr 2021 07:00:11
User opened query 'Per source, ongoing. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:58:53
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '30 Sep 2015'	(b) (4), (b) (6)	27 Apr 2021 06:20:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:58:58
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:20:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Apr 2021 06:20:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 06:20:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Apr 2021 06:20:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:45

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:59:46
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Apr 2021 06:24:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Apr 2021 06:24:53
Data point term sent to Coder	System	27 Apr 2021 06:23:57
User entered 'tramadol'	(b) (4), (b) (6)	27 Apr 2021 06:23:28

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:59:48
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Apr 2021 06:23:28

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:59:50
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'generalized pain'	(b) (4), (b) (6)	27 Apr 2021 06:23:28

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '50'	(b) (4), (b) (6)	27 Apr 2021 06:23:28

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:59:53
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Apr 2021 06:23:28

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:59:55
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:23:28

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:00:50
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'as needed (PRN)'	(b) (4), (b) (6)	27 Apr 2021 06:23:28

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:00:52
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:23:28

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:00:53
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Apr 2021 06:23:28

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:00:55
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:23:28

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:00:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '30 Sep 2016'	(b) (4), (b) (6)	27 Apr 2021 06:23:28

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:45

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:00:58
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:23:28

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:01:00
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Apr 2021 06:23:28

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:01:01
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:23:28

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:01:03
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:23:28

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 06:23:28

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 06:23:28

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 06:23:28

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:22:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CHLORDIAZEPOXIDE, PRODUCTSYNONYM: LIBRIUM [CHLORDIAZEPOXIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 07:39:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 07:39:20
Data point term sent to Coder	System	30 Apr 2021 06:53:52
DataPoint Un-verified.	mathew maran (b) (4) (b) (4)	30 Apr 2021 06:53:21
Coding entries removed.	mathew maran (b) (4) (b) (4)	30 Apr 2021 06:53:21
Signature has been broken.	mathew maran (b) (4) (b) (4)	30 Apr 2021 06:53:21
User entered 'Librium (Chlordiazepoxide)' reason for change: New Information	mathew maran (b) (4) (b) (4)	30 Apr 2021 06:53:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:01:28
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CHLORDIAZEPOXIDE, PRODUCTSYNONYM: LIBRIUM [CHLORDIAZEPOXIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Apr 2021 08:09:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Apr 2021 08:09:16
Data point term sent to Coder	System	27 Apr 2021 06:24:57
User entered 'librium'	(b) (4), (b) (6)	27 Apr 2021 06:24:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:01:50
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:24:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:01:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Alcohol Withdrawal Symptoms'	(b) (4), (b) (6)	27 Apr 2021 06:24:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:01:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '5'	(b) (4), (b) (6)	27 Apr 2021 06:24:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:02:02
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Apr 2021 06:24:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:02:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:24:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:02:06
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'four times daily (QID)'	(b) (4), (b) (6)	27 Apr 2021 06:24:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:02:00
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:24:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:02:12
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Apr 2021 06:24:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:02:14
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:24:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:02:17
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	27 Apr 2021 06:24:54
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Apr 2021 06:24:54
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	27 Apr 2021 06:24:43
User entered '30 Sep 2021'	(b) (4), (b) (6)	27 Apr 2021 06:24:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:45

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:02:19
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:24:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:02:22
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Apr 2021 06:24:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:02:25
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:24:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:02:27
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:24:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	27 Apr 2021 06:24:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 06:24:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Apr 2021 06:24:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:45

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:08:28
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Apr 2021 06:28:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Apr 2021 06:28:01
Data point term sent to Coder	System	27 Apr 2021 06:27:03
User entered 'trazodone'	(b) (4), (b) (6)	27 Apr 2021 06:26:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:08:31
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:26:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:08:32
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'insomnia'	(b) (4), (b) (6)	27 Apr 2021 06:26:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:08:34
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '100'	(b) (4), (b) (6)	27 Apr 2021 06:26:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:08:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Apr 2021 06:26:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:08:38
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:26:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:08:40
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'as needed (PRN)'	(b) (4), (b) (6)	27 Apr 2021 06:26:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:08:42
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:26:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:08:26
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Apr 2021 06:26:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:08:25
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:26:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:08:23
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '14 Apr 2020'	(b) (4), (b) (6)	27 Apr 2021 06:26:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:26:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Apr 2021 06:26:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:26:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:26:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 06:26:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 06:26:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 06:26:43

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:45

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:10:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Apr 2021 06:28:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	27 Apr 2021 06:28:04
Data point term sent to Coder	System	27 Apr 2021 06:27:46
User entered 'protonix'	(b) (4), (b) (6)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:10:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Apr 2021 06:27:46

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:00
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Gastroesophageal Reflux Disease'	(b) (4), (b) (6)	27 Apr 2021 06:27:46

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:02
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '40'	(b) (4), (b) (6)	27 Apr 2021 06:27:46

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:05
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Apr 2021 06:27:46

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:07
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:27:46

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:10
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'twice daily (BID)'	(b) (4), (b) (6)	27 Apr 2021 06:27:46

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:14
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:27:46

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:16
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Apr 2021 06:27:46

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:17
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:27:46

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:19
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '16 Apr 2020'	(b) (4), (b) (6)	27 Apr 2021 06:27:46

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:45

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:20
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:27:46

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:23
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Apr 2021 06:27:46

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:25
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:27:46

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:28
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:27:46

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Apr 2021 06:27:46

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 06:27:46

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Apr 2021 06:27:46

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:14:45

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:40
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Apr 2021 08:10:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	27 Apr 2021 08:10:05
Data point term sent to Coder	System	27 Apr 2021 06:30:05
User entered 'zithromax tab'	(b) (4), (b) (6)	27 Apr 2021 06:29:05

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:42
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:29:05

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:43
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Bilateral multifocal pneumonia right greater than left due to mycoplasma pneumonia'	(b) (4), (b) (6)	27 Apr 2021 06:29:05

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '250'	(b) (4), (b) (6)	27 Apr 2021 06:29:05

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:46
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Apr 2021 06:29:05

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:47
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:29:05

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:49
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Apr 2021 06:29:05

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:29:05

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:52
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Apr 2021 06:29:05

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:54
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:29:05

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:55
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '01 Oct 2020'	(b) (4), (b) (6)	27 Apr 2021 06:29:05

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:14:45

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:29:05

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:11:58
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:29:05

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:12:00
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '04 Oct 2020'	(b) (4), (b) (6)	27 Apr 2021 06:29:05

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:12:01
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:29:05

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 06:29:05

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 06:29:05

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Apr 2021 06:29:05

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:14:45

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:12:08
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Apr 2021 08:10:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	27 Apr 2021 08:10:04
Data point term sent to Coder	System	27 Apr 2021 06:35:06
User entered 'zithromax'	(b) (4), (b) (6)	27 Apr 2021 06:35:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:12:10
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:35:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:12:11
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Bilateral multifocal pneumonia right greater than left due to mycoplasma pneumonia'	(b) (4), (b) (6)	27 Apr 2021 06:35:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:13:50
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '500'	(b) (4), (b) (6)	27 Apr 2021 06:35:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:13:52
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Apr 2021 06:35:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:18:16
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:35:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:18:18
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'once (ONCE)'	(b) (4), (b) (6)	27 Apr 2021 06:35:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:18:19
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:35:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:18:21
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	27 Apr 2021 06:35:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:18:25
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:35:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:14:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:18:23
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '30 Sep 2020'	(b) (4), (b) (6)	27 Apr 2021 06:35:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:14:45

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:18:26
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:35:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:18:28
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:35:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:18:29
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '30 Sep 2020'	(b) (4), (b) (6)	27 Apr 2021 06:35:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:18:31
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:35:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 06:35:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 06:35:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 06:35:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:14:45

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:18:42
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Apr 2021 08:07:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	27 Apr 2021 08:07:59
Data point term sent to Coder	System	27 Apr 2021 06:36:07
User entered 'dexamethasone'	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:18:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:18:46
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Bilateral multifocal pneumonia right greater than left due to mycoplasma pneumonia'	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:18:48
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '6'	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:18:49
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:18:52
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:18:54
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:18:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:18:56
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:01
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:02
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '01 Oct 2020'	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:14:45

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:04
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:07
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:08
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '10 Oct 2020'	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:10
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 06:35:56

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 06:35:56

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Apr 2021 06:35:56

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:14:45

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:23
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Apr 2021 06:38:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	27 Apr 2021 06:38:03
Data point term sent to Coder	System	27 Apr 2021 06:37:08
User entered 'famotidine'	(b) (4), (b) (6)	27 Apr 2021 06:36:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:27
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:36:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:33
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Gastroesophageal Reflux Disease'	(b) (4), (b) (6)	27 Apr 2021 06:36:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:35
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '20'	(b) (4), (b) (6)	27 Apr 2021 06:36:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:39
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Apr 2021 06:36:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:41
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:36:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:42
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Apr 2021 06:36:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:36:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:46
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Apr 2021 06:36:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:47
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 06:36:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:14:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:49
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '01 Oct 2020'	(b) (4), (b) (6)	27 Apr 2021 06:36:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:14:45

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:51
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '0'	(b) (4), (b) (6)	27 Apr 2021 06:36:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:52
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:36:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:54
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '10 Oct 2020'	(b) (4), (b) (6)	27 Apr 2021 06:36:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 18:19:56
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Apr 2021 06:36:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 06:36:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 06:36:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Apr 2021 06:36:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:14:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE, PRODUCTSYNONYM: ALDACTONE [SPIRONOLACTONE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 07:26:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 07:26:20
Data point term sent to Coder	System	30 Apr 2021 06:56:53
User entered 'Aldactone (Spironolactone)'	mathew maran (b) (4) (b) (4)	30 Apr 2021 06:56:49

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'No (N)'	mathew maran (b) (4)	30 Apr 2021 06:56:49
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'Hypertension'	mathew maran (b) (4)	30 Apr 2021 06:56:49
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '30'	mathew maran (b) (4)	30 Apr 2021 06:56:49
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'mg (mg)'	mathew maran (b) (4)	30 Apr 2021 06:56:49
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered empty.	mathew maran (b) (4)	30 Apr 2021 06:56:49
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'once daily (QD)'	mathew maran (b) (4)	30 Apr 2021 06:56:49
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered empty.	mathew maran (b) (4)	30 Apr 2021 06:56:49
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'Oral (ORAL)'	mathew maran (b) (4)	30 Apr 2021 06:56:49
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered empty.	mathew maran (b) (4)	30 Apr 2021 06:56:49
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '30 Sep 2020'	mathew maran (b) (4)	30 Apr 2021 06:56:49
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:14:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '0'	mathew maran (b) (4)	30 Apr 2021 06:56:49
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'No (N)'	mathew maran (b) (4)	30 Apr 2021 06:56:49
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '30 Oct 2020'	mathew maran (b) (4)	30 Apr 2021 06:56:49
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'No (N)'	mathew maran (b) (4)	30 Apr 2021 06:56:49
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 06:56:49

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 06:56:49

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 06:56:49

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:14:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 06:59:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 06:59:18
Data point term sent to Coder	System	30 Apr 2021 06:57:53
User entered 'Furosemide'	mathew maran (b) (4) (b) (4)	30 Apr 2021 06:57:38

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'No (N)'	mathew maran (b) (4)	30 Apr 2021 06:57:38
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'hypertension'	mathew maran (b) (4)	30 Apr 2021 06:57:38
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '20'	mathew maran (b) (4)	30 Apr 2021 06:57:38
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'mg (mg)'	mathew maran (b) (4)	30 Apr 2021 06:57:38
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered empty.	mathew maran (b) (4)	30 Apr 2021 06:57:38
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'once daily (QD)'	mathew maran (b) (4)	30 Apr 2021 06:57:38
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered empty.	mathew maran (b) (4)	30 Apr 2021 06:57:38
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'Oral (ORAL)'	mathew maran (b) (4)	30 Apr 2021 06:57:38
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered empty.	mathew maran (b) (4)	30 Apr 2021 06:57:38
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '30 Sep 2020'	mathew maran (b) (4)	30 Apr 2021 06:57:38
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:14:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '0'	mathew maran (b) (4)	30 Apr 2021 06:57:38
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'No (N)'	mathew maran (b) (4)	30 Apr 2021 06:57:38
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '30 Oct 2020'	mathew maran (b) (4)	30 Apr 2021 06:57:38
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'No (N)'	mathew maran (b) (4)	30 Apr 2021 06:57:38
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 06:57:38

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 06:57:38

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 06:57:38

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:14:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: TUSSI-ORGANIDIN DM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Apr 2021 07:51:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Apr 2021 07:51:20
Data point term sent to Coder	System	30 Apr 2021 07:05:55
User entered 'Tussi-organidin dm-s (Dextromethorphan-Guaifenesin)'	mathew maran (b) (4)	30 Apr 2021 07:05:40

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'No (N)'	mathew maran (b) (4)	30 Apr 2021 07:05:40
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'cough'	mathew maran (b) (4)	30 Apr 2021 07:05:40
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '10-100/ 5'	mathew maran (b) (4)	30 Apr 2021 07:05:40
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'Other (OTHER)'	mathew maran (b) (4)	30 Apr 2021 07:05:40
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'mg/ml'	mathew maran (b) (4)	30 Apr 2021 07:05:40
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'four times daily (QID)'	mathew maran (b) (4)	30 Apr 2021 07:05:40
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered empty.	mathew maran (b) (4)	30 Apr 2021 07:05:40
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'Oral (ORAL)'	mathew maran (b) (4)	30 Apr 2021 07:05:40
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered empty.	mathew maran (b) (4)	30 Apr 2021 07:05:40
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '30 Sep 2020'	mathew maran (b) (4)	30 Apr 2021 07:05:40
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:14:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '0'	mathew maran (b) (4)	30 Apr 2021 07:05:40
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'No (N)'	mathew maran (b) (4)	30 Apr 2021 07:05:40
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '10 Oct 2020'	mathew maran (b) (4)	30 Apr 2021 07:05:40
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'No (N)'	mathew maran (b) (4)	30 Apr 2021 07:05:40
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 07:05:40

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 07:05:40

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 07:05:40

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:14:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: THIAMINE HYDROCHLORIDE, PRODUCTSYNONYM: B1 VITAMIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Apr 2021 07:12:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Apr 2021 07:12:19
Data point term sent to Coder	System	30 Apr 2021 07:11:56
User entered 'B1 vitamin'	mathew maran (b) (4)	30 Apr 2021 07:11:02

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'No (N)'	mathew maran (b) (4)	30 Apr 2021 07:11:02
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'Thiamin deficiency'	mathew maran (b) (4) (b) (4)	30 Apr 2021 07:11:02

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '100'	mathew maran (b) (4)	30 Apr 2021 07:11:02
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'mg (mg)'	mathew maran (b) (4)	30 Apr 2021 07:11:02
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered empty.	mathew maran (b) (4)	30 Apr 2021 07:11:02
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'once daily (QD)'	mathew maran (b) (4)	30 Apr 2021 07:11:02
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered empty.	mathew maran (b) (4)	30 Apr 2021 07:11:02
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'Oral (ORAL)'	mathew maran (b) (4)	30 Apr 2021 07:11:02
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered empty.	mathew maran (b) (4)	30 Apr 2021 07:11:02
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '30 Sep 2020'	mathew maran (b) (4)	30 Apr 2021 07:11:02
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:14:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '0'	mathew maran (b) (4)	30 Apr 2021 07:11:02
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'No (N)'	mathew maran (b) (4)	30 Apr 2021 07:11:02
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '30 Jan 2021'	mathew maran (b) (4)	30 Apr 2021 07:11:02
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'No (N)'	mathew maran (b) (4)	30 Apr 2021 07:11:02
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 07:11:02

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 07:11:02

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 07:11:02

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:14:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: PROAIR HFA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Apr 2021 07:52:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Apr 2021 07:52:20
Data point term sent to Coder	System	30 Apr 2021 07:12:57
User entered 'PROAIR HFA'	mathew maran (b) (4)	30 Apr 2021 07:12:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'No (N)'	mathew maran (b) (4)	30 Apr 2021 07:12:01
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'Shortness of breath'	mathew maran (b) (4)	30 Apr 2021 07:12:01
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '90'	mathew maran (b) (4)	30 Apr 2021 07:12:01
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'ug (ug)'	mathew maran (b) (4) (b) (4)	30 Apr 2021 07:12:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered empty.	mathew maran (b) (4)	30 Apr 2021 07:12:01
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'other (OTHER)'	mathew maran (b) (4)	30 Apr 2021 07:12:01
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '2 puffs every 6 hours'	mathew maran (b) (4)	30 Apr 2021 07:12:01
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	mathew maran (b) (4) (b) (4)	30 Apr 2021 07:12:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered empty.	mathew maran (b) (4)	30 Apr 2021 07:12:01
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '30 Sep 2020'	mathew maran (b) (4)	30 Apr 2021 07:12:01
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:14:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '0'	mathew maran (b) (4)	30 Apr 2021 07:12:01
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'No (N)'	mathew maran (b) (4)	30 Apr 2021 07:12:01
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '10 Oct 2020'	mathew maran (b) (4)	30 Apr 2021 07:12:01
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'No (N)'	mathew maran (b) (4)	30 Apr 2021 07:12:01
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 07:12:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 07:12:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 07:12:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:14:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Apr 2021 07:26:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Apr 2021 07:26:19
Data point term sent to Coder	System	30 Apr 2021 07:12:58
User entered 'Lantus Solostar'	mathew maran (b) (4)	30 Apr 2021 07:12:50

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:14:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'No (N)'	mathew maran (b) (4)	30 Apr 2021 07:12:50
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'Type 2 diabetes mellitus'	mathew maran (b) (4)	30 Apr 2021 07:12:50
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:14:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '10'	mathew maran (b) (4)	30 Apr 2021 07:12:50
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:14:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'IU (IU)'	mathew maran (b) (4)	30 Apr 2021 07:12:50
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:14:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered empty.	mathew maran (b) (4)	30 Apr 2021 07:12:50
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:14:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'once daily (QD)'	mathew maran (b) (4)	30 Apr 2021 07:12:50
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:14:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered empty.	mathew maran (b) (4)	30 Apr 2021 07:12:50
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:14:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'Subcutaneous (SUBCUTANEOUS)'	mathew maran (b) (4)	30 Apr 2021 07:12:50
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:14:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered empty.	mathew maran (b) (4)	30 Apr 2021 07:12:50
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:14:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '30 Sep 2020'	mathew maran (b) (4)	30 Apr 2021 07:12:50
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:14:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '0'	mathew maran (b) (4)	30 Apr 2021 07:12:50
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:14:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'No (N)'	mathew maran (b) (4)	30 Apr 2021 07:12:50
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:14:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered '10 Oct 2020'	mathew maran (b) (4)	30 Apr 2021 07:12:50
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:14:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
User entered 'No (N)'	mathew maran (b) (4)	30 Apr 2021 07:12:50
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:14:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 07:12:50

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 07:12:50

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:14:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 07:12:50

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:14:45

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:40:49
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:05:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 06:49:59
Signature has been broken.		27 Apr 2021 06:49:59
User entered 'Yes (Y)' reason for change: Data Entry Error		27 Apr 2021 06:49:59
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:09:26
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:22:33
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:34:27

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:14:45

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:38:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '30 Sep 2020'	(b) (4), (b) (6)	27 Apr 2021 07:07:03

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:14:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:38:59
User entered 'Abdominal Ultrasound' reason for change: Data Entry Error	mathew maran (b) (4)	30 Apr 2021 06:46:08
Signature has been broken.	(b) (4)	
	mathew maran (b) (4)	30 Apr 2021 06:45:39
	(b) (4)	
User entered 'Abdominal Distention/Cirrhosis/possible ascites' reason for change: Data Entry Error	mathew maran (b) (4)	30 Apr 2021 06:45:39
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'procedure'	(b) (4), (b) (6)	27 Apr 2021 07:07:03

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:39:00
Signature has been broken.	mathew maran (b) (4)	30 Apr 2021 06:44:48
	(b) (4)	
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	mathew maran (b) (4)	30 Apr 2021 06:44:48
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Other (OTHER)'	(b) (4), (b) (6)	27 Apr 2021 07:07:03

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:14:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:39:02
Signature has been broken.	mathew maran (b) (4)	30 Apr 2021 06:44:48
	(b) (4)	
User entered empty; reason for change Data Entry Error	mathew maran (b) (4)	30 Apr 2021 06:44:48
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered 'Abdominal Distention/Cirrhosis/possible ascites'	(b) (4), (b) (6)	27 Apr 2021 07:07:03

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:14:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:39:16
User entered '30 Sep 2020'	mathew maran (b) (4)	30 Apr 2021 06:46:29
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:14:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:39:17
User entered 'Chest X-ray'	mathew maran (b) (4)	30 Apr 2021 06:46:29
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:39:19
User entered 'Adverse Event (AE)'	mathew maran (b) (4)	30 Apr 2021 06:46:29
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:14:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:39:20
User entered empty.	mathew maran (b) (4)	30 Apr 2021 06:46:29
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:14:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:39:32
User entered '30 Sep 2020'	mathew maran (b) (4)	30 Apr 2021 06:46:48
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:14:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:40:51
User entered 'Ultrasound of the Kidneys and Urinary Bladder'	mathew maran (b) (4)	30 Apr 2021 06:46:48

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:40:53
User entered 'Adverse Event (AE)'	mathew maran (b) (4)	30 Apr 2021 06:46:48
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:14:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:40:55
User entered empty.	mathew maran (b) (4) (b) (4)	30 Apr 2021 06:46:48

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:14:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:04
User entered '01 Oct 2020'	mathew maran (b) (4)	30 Apr 2021 06:47:12
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:14:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:08
User entered 'Computed Tomography Angiogram Chest with IV Contrast'	mathew maran (b) (4)	30 Apr 2021 06:47:12

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:10
User entered 'Adverse Event (AE)'	mathew maran (b) (4)	30 Apr 2021 06:47:12
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:14:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:11
User entered empty.	mathew maran (b) (4)	30 Apr 2021 06:47:12
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:14:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:15
User entered '02 Oct 2020'	mathew maran (b) (4)	30 Apr 2021 06:47:33
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:14:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:17
User entered 'Transthoracic Echocardiogram'	mathew maran (b) (4) (b) (4)	30 Apr 2021 06:47:33

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:19
User entered 'Adverse Event (AE)'	mathew maran (b) (4)	30 Apr 2021 06:47:33
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:14:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:21
User entered empty.	mathew maran (b) (4)	30 Apr 2021 06:47:33
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:14:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:25
User entered '04 Oct 2020'	mathew maran (b) (4)	30 Apr 2021 06:47:51
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:14:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:26
User entered 'Chest X-Ray'	mathew maran (b) (4)	30 Apr 2021 06:47:51
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:28
User entered 'Adverse Event (AE)'	mathew maran (b) (4) (b) (4)	30 Apr 2021 06:47:51

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:14:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:29
User entered empty.	mathew maran (b) (4)	30 Apr 2021 06:47:51
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:14:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:32
User entered '04 Oct 2020'	mathew maran (b) (4)	30 Apr 2021 06:48:11
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:14:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:34
User entered 'Computed Tomography of the Abdomen/Pelvis w/o Contrast'	mathew maran (b) (4)	30 Apr 2021 06:48:11

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:35
User entered 'Adverse Event (AE)'	mathew maran (b) (4)	30 Apr 2021 06:48:11
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:14:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:37
User entered empty.	mathew maran (b) (4)	30 Apr 2021 06:48:11
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:14:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:40
User entered '05 Oct 2020'	mathew maran (b) (4)	30 Apr 2021 06:48:37
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:14:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:41
User entered 'Ultrasound Paracentesis with image'	mathew maran (b) (4)	30 Apr 2021 06:48:37
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:43
User entered 'Adverse Event (AE)'	mathew maran (b) (4)	30 Apr 2021 06:48:37
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:14:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:44
User entered empty.	mathew maran (b) (4)	30 Apr 2021 06:48:37
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:14:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:47
User entered '05 Oct 2020'	mathew maran (b) (4)	30 Apr 2021 06:48:53
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:14:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:48
User entered 'Abdominal X-ray'	mathew maran (b) (4)	30 Apr 2021 06:48:53
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:50
User entered 'Adverse Event (AE)'	mathew maran (b) (4)	30 Apr 2021 06:48:53
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:14:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:51
User entered empty.	mathew maran (b) (4)	30 Apr 2021 06:48:53
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:14:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:54
User entered '06 Oct 2020'	mathew maran (b) (4)	30 Apr 2021 06:49:10
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:14:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:55
User entered 'Right Colon Biopsy'	mathew maran (b) (4)	30 Apr 2021 06:49:10
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:57
User entered 'Adverse Event (AE)'	mathew maran (b) (4)	30 Apr 2021 06:49:10
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:14:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:58
User entered empty.	mathew maran (b) (4)	30 Apr 2021 06:49:10
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 16:14:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:40:13
User entered '06 Oct 2020'	mathew maran (b) (4)	30 Apr 2021 06:49:24
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 16:14:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:40:15
User entered 'Left Colon Biopsy'	mathew maran (b) (4)	30 Apr 2021 06:49:24
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:40:16
User entered 'Adverse Event (AE)'	mathew maran (b) (4)	30 Apr 2021 06:49:24
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 16:14:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:40:18
User entered empty.	mathew maran (b) (4)	30 Apr 2021 06:49:24
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 16:14:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:40:25
User entered '06 Oct 2020'	mathew maran (b) (4)	30 Apr 2021 06:49:43
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 16:14:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:40:26
User entered 'Colonoscopy'	mathew maran (b) (4)	30 Apr 2021 06:49:43
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:40:28
User entered 'Adverse Event (AE)'	mathew maran (b) (4)	30 Apr 2021 06:49:43
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 16:14:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:40:30
User entered empty.	mathew maran (b) (4)	30 Apr 2021 06:49:43
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 16:14:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:40:34
User entered '07 Oct 2020'	mathew maran (b) (4)	30 Apr 2021 06:49:58
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 16:14:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:40:36
User entered 'Abdominal X-ray'	mathew maran (b) (4)	30 Apr 2021 06:49:58
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 16:14:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:40:38
User entered 'Adverse Event (AE)'	mathew maran (b) (4)	30 Apr 2021 06:49:58
	(b) (4)	

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 16:14:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:28:26
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:40:40
User entered empty.	mathew maran (b) (4)	30 Apr 2021 06:49:58
	(b) (4)	

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:41:30
DataPoint Un-verified.	System	13 Apr 2021 17:15:46
Signature has been broken.	System	13 Apr 2021 17:15:46
User entered 'carmpa'	System	13 Apr 2021 17:15:46
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 16:26:39
User closed query 'Please update to the correct site postal code.' (Site from CRA).		23 Mar 2021 16:26:37
Query 'Please update to the correct site postal code.' answered with 'Updated' (Site from CRA).		09 Mar 2021 05:51:00
Un-reviewed for Safety.		09 Mar 2021 05:49:59
User entered '78504' reason for change: Data Entry Error		09 Mar 2021 05:49:59
User opened query 'Please update to the correct site postal code.' (Site from CRA).		26 Feb 2021 20:55:19
DataPoint Un-verified.		26 Feb 2021 20:55:05
DataPoint Verified.		08 Jan 2021 04:54:58
Reviewed for Safety.		13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '14'	System	26 Apr 2021 17:08:49
User entered '13'	System	23 Apr 2021 19:32:40
User entered '12'	System	22 Apr 2021 20:07:37
User entered '11'	System	19 Apr 2021 13:41:49
User entered '10'	System	13 Apr 2021 17:15:46
User entered '9'	System	08 Mar 2021 14:53:57
User entered '8'	System	26 Feb 2021 16:15:03
User entered '7'	System	18 Feb 2021 20:59:15
User entered '6'	System	11 Feb 2021 14:14:01
User entered '5'	System	25 Nov 2020 13:26:36
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:41:30
DataPoint Un-verified.	System	13 Apr 2021 17:15:46
Signature has been broken.	System	13 Apr 2021 17:15:46
User entered 'carmpa'	System	13 Apr 2021 17:15:46
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 16:26:39
User closed query 'Please update to the correct site postal code.' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 16:26:37
Query 'Please update to the correct site postal code.' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 05:51:00
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 05:49:59
User entered '78504' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 05:49:59
User opened query 'Please update to the correct site postal code.' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 20:55:19
DataPoint Un-verified.	(b) (4), (b) (6)	26 Feb 2021 20:55:05
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '14'	System	26 Apr 2021 17:08:49
User entered '13'	System	23 Apr 2021 19:32:40
User entered '12'	System	22 Apr 2021 20:07:37
User entered '11'	System	19 Apr 2021 13:41:49
User entered '10'	System	13 Apr 2021 17:15:46
User entered '9'	System	08 Mar 2021 14:53:57
User entered '8'	System	26 Feb 2021 16:15:03
User entered '7'	System	18 Feb 2021 20:59:15
User entered '6'	System	11 Feb 2021 14:14:01
User entered '5'	System	25 Nov 2020 13:26:36
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:14:45

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
User entered '13/Oct/2020 10:00'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:14:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered '1'	(b) (4), (b) (6)	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:41:30
DataPoint Un-verified.	System	13 Apr 2021 17:15:46
Signature has been broken.	System	13 Apr 2021 17:15:46
User entered 'carmpa'	System	13 Apr 2021 17:15:46
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 16:26:39
User closed query 'Please update to the correct site postal code.' (Site from CRA).		23 Mar 2021 16:26:37
Query 'Please update to the correct site postal code.' answered with 'Updated' (Site from CRA).		09 Mar 2021 05:51:00
Un-reviewed for Safety.		09 Mar 2021 05:49:59
User entered '78504' reason for change: Data Entry Error		09 Mar 2021 05:49:59
User opened query 'Please update to the correct site postal code.' (Site from CRA).		26 Feb 2021 20:55:19
DataPoint Un-verified.		26 Feb 2021 20:55:05
DataPoint Verified.		08 Jan 2021 04:54:58
Reviewed for Safety.		13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '14'	System	26 Apr 2021 17:08:49
User entered '13'	System	23 Apr 2021 19:32:40
User entered '12'	System	22 Apr 2021 20:07:37
User entered '11'	System	19 Apr 2021 13:41:49
User entered '10'	System	13 Apr 2021 17:15:46
User entered '9'	System	08 Mar 2021 14:53:57
User entered '8'	System	26 Feb 2021 16:15:03
User entered '7'	System	18 Feb 2021 20:59:15
User entered '6'	System	11 Feb 2021 14:14:01
User entered '5'	System	25 Nov 2020 13:26:36
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:14:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
User entered '21/Oct/2020 20:14'	System	21 Oct 2020 20:14:03

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:14:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:30:26
User entered '1'	(b) (4), (b) (6)	21 Oct 2020 20:14:03

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:41:30
DataPoint Un-verified.	System	13 Apr 2021 17:15:46
Signature has been broken.	System	13 Apr 2021 17:15:46
User entered 'carmpa'	System	13 Apr 2021 17:15:46
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 16:26:39
User closed query 'Please update to the correct site postal code.' (Site from CRA).		23 Mar 2021 16:26:37
Query 'Please update to the correct site postal code.' answered with 'Updated' (Site from CRA).		09 Mar 2021 05:51:00
Un-reviewed for Safety.		09 Mar 2021 05:49:59
User entered '78504' reason for change: Data Entry Error		09 Mar 2021 05:49:59
User opened query 'Please update to the correct site postal code.' (Site from CRA).		26 Feb 2021 20:55:19
DataPoint Un-verified.		26 Feb 2021 20:55:05
DataPoint Verified.		08 Jan 2021 04:54:58
Reviewed for Safety.		13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '14'	System	26 Apr 2021 17:08:49
User entered '13'	System	23 Apr 2021 19:32:40
User entered '12'	System	22 Apr 2021 20:07:37
User entered '11'	System	19 Apr 2021 13:41:49
User entered '10'	System	13 Apr 2021 17:15:46
User entered '9'	System	08 Mar 2021 14:53:57
User entered '8'	System	26 Feb 2021 16:15:03
User entered '7'	System	18 Feb 2021 20:59:15
User entered '6'	System	11 Feb 2021 14:14:01
User entered '5'	System	25 Nov 2020 13:26:36
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:14:45

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
User entered '21/Oct/2020 20:30'	System	21 Oct 2020 20:30:52

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:14:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:19:24
User entered '1'	(b) (4), (b) (6)	21 Oct 2020 20:30:52

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:41:30
DataPoint Un-verified.	System	13 Apr 2021 17:15:46
Signature has been broken.	System	13 Apr 2021 17:15:46
User entered 'carmpa'	System	13 Apr 2021 17:15:46
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 16:26:39
User closed query 'Please update to the correct site postal code.' (Site from CRA).		23 Mar 2021 16:26:37
Query 'Please update to the correct site postal code.' answered with 'Updated' (Site from CRA).		09 Mar 2021 05:51:00
Un-reviewed for Safety.		09 Mar 2021 05:49:59
User entered '78504' reason for change: Data Entry Error		09 Mar 2021 05:49:59
User opened query 'Please update to the correct site postal code.' (Site from CRA).		26 Feb 2021 20:55:19
DataPoint Un-verified.		26 Feb 2021 20:55:05
DataPoint Verified.		08 Jan 2021 04:54:58
Reviewed for Safety.		13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '14'	System	26 Apr 2021 17:08:49
User entered '13'	System	23 Apr 2021 19:32:40
User entered '12'	System	22 Apr 2021 20:07:37
User entered '11'	System	19 Apr 2021 13:41:49
User entered '10'	System	13 Apr 2021 17:15:46
User entered '9'	System	08 Mar 2021 14:53:57
User entered '8'	System	26 Feb 2021 16:15:03
User entered '7'	System	18 Feb 2021 20:59:15
User entered '6'	System	11 Feb 2021 14:14:01
User entered '5'	System	25 Nov 2020 13:26:36
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:14:45

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
User entered '22/Oct/2020 14:19'	System	22 Oct 2020 14:19:50

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:14:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:20:58
User entered '1'	(b) (4), (b) (6)	22 Oct 2020 14:19:50

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:41:30
DataPoint Un-verified.	System	13 Apr 2021 17:15:46
Signature has been broken.	System	13 Apr 2021 17:15:46
User entered 'carmpa'	System	13 Apr 2021 17:15:46
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 16:26:39
User closed query 'Please update to the correct site postal code.' (Site from CRA).		23 Mar 2021 16:26:37
Query 'Please update to the correct site postal code.' answered with 'Updated' (Site from CRA).		09 Mar 2021 05:51:00
Un-reviewed for Safety.		09 Mar 2021 05:49:59
User entered '78504' reason for change: Data Entry Error		09 Mar 2021 05:49:59
User opened query 'Please update to the correct site postal code.' (Site from CRA).		26 Feb 2021 20:55:19
DataPoint Un-verified.		26 Feb 2021 20:55:05
DataPoint Verified.		08 Jan 2021 04:54:58
Reviewed for Safety.		13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '14'	System	26 Apr 2021 17:08:49
User entered '13'	System	23 Apr 2021 19:32:40
User entered '12'	System	22 Apr 2021 20:07:37
User entered '11'	System	19 Apr 2021 13:41:49
User entered '10'	System	13 Apr 2021 17:15:46
User entered '9'	System	08 Mar 2021 14:53:57
User entered '8'	System	26 Feb 2021 16:15:03
User entered '7'	System	18 Feb 2021 20:59:15
User entered '6'	System	11 Feb 2021 14:14:01
User entered '5'	System	25 Nov 2020 13:26:36
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:14:45

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
User entered '25/Nov/2020 13:26'	System	25 Nov 2020 13:26:36

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:14:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:13:46
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 13:26:36

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:41:30
DataPoint Un-verified.	System	13 Apr 2021 17:15:46
Signature has been broken.	System	13 Apr 2021 17:15:46
User entered 'carmpa'	System	13 Apr 2021 17:15:46
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 16:26:39
User closed query 'Please update to the correct site postal code.' (Site from CRA).		23 Mar 2021 16:26:37
Query 'Please update to the correct site postal code.' answered with 'Updated' (Site from CRA).		09 Mar 2021 05:51:00
Un-reviewed for Safety.		09 Mar 2021 05:49:59
User entered '78504' reason for change: Data Entry Error		09 Mar 2021 05:49:59
User opened query 'Please update to the correct site postal code.' (Site from CRA).		26 Feb 2021 20:55:19
DataPoint Un-verified.		26 Feb 2021 20:55:05
DataPoint Verified.		08 Jan 2021 04:54:58
Reviewed for Safety.		13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '14'	System	26 Apr 2021 17:08:49
User entered '13'	System	23 Apr 2021 19:32:40
User entered '12'	System	22 Apr 2021 20:07:37
User entered '11'	System	19 Apr 2021 13:41:49
User entered '10'	System	13 Apr 2021 17:15:46
User entered '9'	System	08 Mar 2021 14:53:57
User entered '8'	System	26 Feb 2021 16:15:03
User entered '7'	System	18 Feb 2021 20:59:15
User entered '6'	System	11 Feb 2021 14:14:01
User entered '5'	System	25 Nov 2020 13:26:36
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:14:45

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:55:45
User entered '11/Feb/2021 09:13'	System	11 Feb 2021 14:14:01

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:14:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:55:44
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:59:49
User entered '1'	(b) (4), (b) (6)	11 Feb 2021 14:14:01

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:41:30
DataPoint Un-verified.	System	13 Apr 2021 17:15:46
Signature has been broken.	System	13 Apr 2021 17:15:46
User entered 'carmpa'	System	13 Apr 2021 17:15:46
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 16:26:39
User closed query 'Please update to the correct site postal code.' (Site from CRA).		23 Mar 2021 16:26:37
Query 'Please update to the correct site postal code.' answered with 'Updated' (Site from CRA).		09 Mar 2021 05:51:00
Un-reviewed for Safety.		09 Mar 2021 05:49:59
User entered '78504' reason for change: Data Entry Error		09 Mar 2021 05:49:59
User opened query 'Please update to the correct site postal code.' (Site from CRA).		26 Feb 2021 20:55:19
DataPoint Un-verified.		26 Feb 2021 20:55:05
DataPoint Verified.		08 Jan 2021 04:54:58
Reviewed for Safety.		13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '14'	System	26 Apr 2021 17:08:49
User entered '13'	System	23 Apr 2021 19:32:40
User entered '12'	System	22 Apr 2021 20:07:37
User entered '11'	System	19 Apr 2021 13:41:49
User entered '10'	System	13 Apr 2021 17:15:46
User entered '9'	System	08 Mar 2021 14:53:57
User entered '8'	System	26 Feb 2021 16:15:03
User entered '7'	System	18 Feb 2021 20:59:15
User entered '6'	System	11 Feb 2021 14:14:01
User entered '5'	System	25 Nov 2020 13:26:36
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:14:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:55:37
User entered '18/Feb/2021 15:59'	System	18 Feb 2021 20:59:15

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:14:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:55:35
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:59:49
User entered '1'	(b) (4), (b) (6)	18 Feb 2021 20:59:15

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:41:30
DataPoint Un-verified.	System	13 Apr 2021 17:15:46
Signature has been broken.	System	13 Apr 2021 17:15:46
User entered 'carmpa'	System	13 Apr 2021 17:15:46
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 16:26:39
User closed query 'Please update to the correct site postal code.' (Site from CRA).		23 Mar 2021 16:26:37
Query 'Please update to the correct site postal code.' answered with 'Updated' (Site from CRA).		09 Mar 2021 05:51:00
Un-reviewed for Safety.		09 Mar 2021 05:49:59
User entered '78504' reason for change: Data Entry Error		09 Mar 2021 05:49:59
User opened query 'Please update to the correct site postal code.' (Site from CRA).		26 Feb 2021 20:55:19
DataPoint Un-verified.		26 Feb 2021 20:55:05
DataPoint Verified.		08 Jan 2021 04:54:58
Reviewed for Safety.		13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '14'	System	26 Apr 2021 17:08:49
User entered '13'	System	23 Apr 2021 19:32:40
User entered '12'	System	22 Apr 2021 20:07:37
User entered '11'	System	19 Apr 2021 13:41:49
User entered '10'	System	13 Apr 2021 17:15:46
User entered '9'	System	08 Mar 2021 14:53:57
User entered '8'	System	26 Feb 2021 16:15:03
User entered '7'	System	18 Feb 2021 20:59:15
User entered '6'	System	11 Feb 2021 14:14:01
User entered '5'	System	25 Nov 2020 13:26:36
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:14:45

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:55:26
User entered '26/Feb/2021 10:14'	System	26 Feb 2021 16:15:03

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:14:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:53:41
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 20:55:28
User entered '1'	(b) (4), (b) (6)	26 Feb 2021 16:15:03

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:41:30
DataPoint Un-verified.	System	13 Apr 2021 17:15:46
Signature has been broken.	System	13 Apr 2021 17:15:46
User entered 'carmpa'	System	13 Apr 2021 17:15:46
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 16:26:39
User closed query 'Please update to the correct site postal code.' (Site from CRA).		23 Mar 2021 16:26:37
Query 'Please update to the correct site postal code.' answered with 'Updated' (Site from CRA).		09 Mar 2021 05:51:00
Un-reviewed for Safety.		09 Mar 2021 05:49:59
User entered '78504' reason for change: Data Entry Error		09 Mar 2021 05:49:59
User opened query 'Please update to the correct site postal code.' (Site from CRA).		26 Feb 2021 20:55:19
DataPoint Un-verified.		26 Feb 2021 20:55:05
DataPoint Verified.		08 Jan 2021 04:54:58
Reviewed for Safety.		13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '14'	System	26 Apr 2021 17:08:49
User entered '13'	System	23 Apr 2021 19:32:40
User entered '12'	System	22 Apr 2021 20:07:37
User entered '11'	System	19 Apr 2021 13:41:49
User entered '10'	System	13 Apr 2021 17:15:46
User entered '9'	System	08 Mar 2021 14:53:57
User entered '8'	System	26 Feb 2021 16:15:03
User entered '7'	System	18 Feb 2021 20:59:15
User entered '6'	System	11 Feb 2021 14:14:01
User entered '5'	System	25 Nov 2020 13:26:36
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:14:45

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:00:01
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
User entered '08/Mar/2021 09:53'	System	08 Mar 2021 14:53:57

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:14:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:00:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:41:30
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
User entered '1'	(b) (4), (b) (6)	08 Mar 2021 14:53:57

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:41:30
DataPoint Un-verified.	System	13 Apr 2021 17:15:46
Signature has been broken.	System	13 Apr 2021 17:15:46
User entered 'carmpa'	System	13 Apr 2021 17:15:46
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 16:26:39
User closed query 'Please update to the correct site postal code.' (Site from CRA).		23 Mar 2021 16:26:37
Query 'Please update to the correct site postal code.' answered with 'Updated' (Site from CRA).		09 Mar 2021 05:51:00
Un-reviewed for Safety.		09 Mar 2021 05:49:59
User entered '78504' reason for change: Data Entry Error		09 Mar 2021 05:49:59
User opened query 'Please update to the correct site postal code.' (Site from CRA).		26 Feb 2021 20:55:19
DataPoint Un-verified.		26 Feb 2021 20:55:05
DataPoint Verified.		08 Jan 2021 04:54:58
Reviewed for Safety.		13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '14'	System	26 Apr 2021 17:08:49
User entered '13'	System	23 Apr 2021 19:32:40
User entered '12'	System	22 Apr 2021 20:07:37
User entered '11'	System	19 Apr 2021 13:41:49
User entered '10'	System	13 Apr 2021 17:15:46
User entered '9'	System	08 Mar 2021 14:53:57
User entered '8'	System	26 Feb 2021 16:15:03
User entered '7'	System	18 Feb 2021 20:59:15
User entered '6'	System	11 Feb 2021 14:14:01
User entered '5'	System	25 Nov 2020 13:26:36
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 16:14:45

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:00:01
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '13/Apr/2021 13:15'	System	13 Apr 2021 17:15:46

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 16:14:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:00:01
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:41:30
User entered '1'	(b) (4), (b) (6)	13 Apr 2021 17:15:46

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:41:30
DataPoint Un-verified.	System	13 Apr 2021 17:15:46
Signature has been broken.	System	13 Apr 2021 17:15:46
User entered 'carmpa'	System	13 Apr 2021 17:15:46
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 16:26:39
User closed query 'Please update to the correct site postal code.' (Site from CRA).		23 Mar 2021 16:26:37
Query 'Please update to the correct site postal code.' answered with 'Updated' (Site from CRA).		09 Mar 2021 05:51:00
Un-reviewed for Safety.		09 Mar 2021 05:49:59
User entered '78504' reason for change: Data Entry Error		09 Mar 2021 05:49:59
User opened query 'Please update to the correct site postal code.' (Site from CRA).		26 Feb 2021 20:55:19
DataPoint Un-verified.		26 Feb 2021 20:55:05
DataPoint Verified.		08 Jan 2021 04:54:58
Reviewed for Safety.		13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '14'	System	26 Apr 2021 17:08:49
User entered '13'	System	23 Apr 2021 19:32:40
User entered '12'	System	22 Apr 2021 20:07:37
User entered '11'	System	19 Apr 2021 13:41:49
User entered '10'	System	13 Apr 2021 17:15:46
User entered '9'	System	08 Mar 2021 14:53:57
User entered '8'	System	26 Feb 2021 16:15:03
User entered '7'	System	18 Feb 2021 20:59:15
User entered '6'	System	11 Feb 2021 14:14:01
User entered '5'	System	25 Nov 2020 13:26:36
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 16:14:45

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:00:01
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '19/Apr/2021 09:41'	System	19 Apr 2021 13:41:49

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 16:14:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 17:08:26
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:00:01
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '1'	(b) (4), (b) (6)	19 Apr 2021 13:41:49

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:41:30
DataPoint Un-verified.	System	13 Apr 2021 17:15:46
Signature has been broken.	System	13 Apr 2021 17:15:46
User entered 'carmpa'	System	13 Apr 2021 17:15:46
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 16:26:39
User closed query 'Please update to the correct site postal code.' (Site from CRA).		23 Mar 2021 16:26:37
Query 'Please update to the correct site postal code.' answered with 'Updated' (Site from CRA).		09 Mar 2021 05:51:00
Un-reviewed for Safety.		09 Mar 2021 05:49:59
User entered '78504' reason for change: Data Entry Error		09 Mar 2021 05:49:59
User opened query 'Please update to the correct site postal code.' (Site from CRA).		26 Feb 2021 20:55:19
DataPoint Un-verified.		26 Feb 2021 20:55:05
DataPoint Verified.		08 Jan 2021 04:54:58
Reviewed for Safety.		13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '14'	System	26 Apr 2021 17:08:49
User entered '13'	System	23 Apr 2021 19:32:40
User entered '12'	System	22 Apr 2021 20:07:37
User entered '11'	System	19 Apr 2021 13:41:49
User entered '10'	System	13 Apr 2021 17:15:46
User entered '9'	System	08 Mar 2021 14:53:57
User entered '8'	System	26 Feb 2021 16:15:03
User entered '7'	System	18 Feb 2021 20:59:15
User entered '6'	System	11 Feb 2021 14:14:01
User entered '5'	System	25 Nov 2020 13:26:36
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 16:14:45

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:00:01
User entered '22/Apr/2021 13:07'	System	22 Apr 2021 20:07:37

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 16:14:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 17:08:26
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:00:01
User entered '1'	(b) (4), (b) (6)	22 Apr 2021 20:07:37

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:41:30
DataPoint Un-verified.	System	13 Apr 2021 17:15:46
Signature has been broken.	System	13 Apr 2021 17:15:46
User entered 'carmpa'	System	13 Apr 2021 17:15:46
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 16:26:39
User closed query 'Please update to the correct site postal code.' (Site from CRA).		23 Mar 2021 16:26:37
Query 'Please update to the correct site postal code.' answered with 'Updated' (Site from CRA).		09 Mar 2021 05:51:00
Un-reviewed for Safety.		09 Mar 2021 05:49:59
User entered '78504' reason for change: Data Entry Error		09 Mar 2021 05:49:59
User opened query 'Please update to the correct site postal code.' (Site from CRA).		26 Feb 2021 20:55:19
DataPoint Un-verified.		26 Feb 2021 20:55:05
DataPoint Verified.		08 Jan 2021 04:54:58
Reviewed for Safety.		13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '14'	System	26 Apr 2021 17:08:49
User entered '13'	System	23 Apr 2021 19:32:40
User entered '12'	System	22 Apr 2021 20:07:37
User entered '11'	System	19 Apr 2021 13:41:49
User entered '10'	System	13 Apr 2021 17:15:46
User entered '9'	System	08 Mar 2021 14:53:57
User entered '8'	System	26 Feb 2021 16:15:03
User entered '7'	System	18 Feb 2021 20:59:15
User entered '6'	System	11 Feb 2021 14:14:01
User entered '5'	System	25 Nov 2020 13:26:36
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 16:14:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:03:25
User entered '23/Apr/2021 12:32'	System	23 Apr 2021 19:32:40

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 16:14:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 17:08:26
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:03:25
User entered '1'	(b) (4), (b) (6)	23 Apr 2021 19:32:40

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:41:30
DataPoint Un-verified.	System	13 Apr 2021 17:15:46
Signature has been broken.	System	13 Apr 2021 17:15:46
User entered 'carmpa'	System	13 Apr 2021 17:15:46
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 16:26:39
User closed query 'Please update to the correct site postal code.' (Site from CRA).		23 Mar 2021 16:26:37
Query 'Please update to the correct site postal code.' answered with 'Updated' (Site from CRA).		09 Mar 2021 05:51:00
Un-reviewed for Safety.		09 Mar 2021 05:49:59
User entered '78504' reason for change: Data Entry Error		09 Mar 2021 05:49:59
User opened query 'Please update to the correct site postal code.' (Site from CRA).		26 Feb 2021 20:55:19
DataPoint Un-verified.		26 Feb 2021 20:55:05
DataPoint Verified.		08 Jan 2021 04:54:58
Reviewed for Safety.		13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 20:40:41
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 04:54:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '14'	System	26 Apr 2021 17:08:49
User entered '13'	System	23 Apr 2021 19:32:40
User entered '12'	System	22 Apr 2021 20:07:37
User entered '11'	System	19 Apr 2021 13:41:49
User entered '10'	System	13 Apr 2021 17:15:46
User entered '9'	System	08 Mar 2021 14:53:57
User entered '8'	System	26 Feb 2021 16:15:03
User entered '7'	System	18 Feb 2021 20:59:15
User entered '6'	System	11 Feb 2021 14:14:01
User entered '5'	System	25 Nov 2020 13:26:36
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (14)

Generated On: 09 Jun 2021 16:14:45

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:04:56
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '26/Apr/2021 17:08'	System	26 Apr 2021 17:08:49

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (14)

Generated On: 09 Jun 2021 16:14:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:04:56
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
User entered '1'	(b) (4), (b) (6)	26 Apr 2021 17:08:49

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'USA-US108-2021-MRNA-1273-P301000020'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Yes (Y)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Yes (Y)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Joel'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Solis'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered '5201 N. 10th Street'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Mcallen'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'TX'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'carmpa'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'US'	System	19 Apr 2021 14:08:17

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Apr 2021 19:06:32
User entered '2'	System	22 Apr 2021 19:27:05
User entered '1'	System	19 Apr 2021 14:08:17

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'USA-US108-2021-MRNA-1273-P301000020'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Yes (Y)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Yes (Y)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Joel'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Solis'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered '5201 N. 10th Street'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Mcallen'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'TX'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'carmpa'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'US'	System	19 Apr 2021 14:08:17

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Apr 2021 19:06:32
User entered '2'	System	22 Apr 2021 19:27:05
User entered '1'	System	19 Apr 2021 14:08:17

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:14:45

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '19/Apr/2021 10:08'	System	19 Apr 2021 14:08:17

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:14:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered '1'	(b) (4), (b) (6)	19 Apr 2021 14:08:17

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'USA-US108-2021-MRNA-1273-P301000020'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Yes (Y)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Yes (Y)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Joel'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Solis'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered '5201 N. 10th Street'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Mcallen'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'TX'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'carmpa'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'US'	System	19 Apr 2021 14:08:17

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Apr 2021 19:06:32
User entered '2'	System	22 Apr 2021 19:27:05
User entered '1'	System	19 Apr 2021 14:08:17

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:14:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User entered '22/Apr/2021 12:26'	System	22 Apr 2021 19:27:05

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:14:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User entered 'I'	(b) (4), (b) (6)	22 Apr 2021 19:27:05

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'USA-US108-2021-MRNA-1273-P301000020'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Yes (Y)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Yes (Y)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'No (N)'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Joel'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Solis'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered '5201 N. 10th Street'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'Mcallen'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'TX'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:07:51
User entered 'carmpa'	System	19 Apr 2021 14:05:57

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:04:38
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:04:16
User entered 'US'	System	19 Apr 2021 14:08:17

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Apr 2021 19:06:32
User entered '2'	System	22 Apr 2021 19:27:05
User entered '1'	System	19 Apr 2021 14:08:17

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:14:45

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:03:30
User entered '23/Apr/2021 12:06'	System	23 Apr 2021 19:06:32

US3252516

Folder: SAE USA-US108-2021-MRNA-1273-P301000020

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:14:45

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:45:17
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 21:03:30
User entered 'I'	(b) (4), (b) (6)	23 Apr 2021 19:06:32